

PACKAGE LEAFLET: INFORMATION FOR THE USER

# NAPROXEN

## 250 mg & 500 mg

### GASTRO-RESISTANT TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### WHAT IS IN THIS LEAFLET

1. What Naproxen Tablets is and what it is used for
2. What you need to know before you take Naproxen Tablets
3. How to take Naproxen Tablets
4. Possible side effects
5. How to store Naproxen Tablets
6. Contents of the pack and other information

#### 1. WHAT NAPROXEN TABLETS IS AND WHAT IT IS USED FOR

Naproxen is a Non-Steroidal Anti-Inflammatory Drug (NSAID) used to reduce pain and swelling in joint, bone or muscle diseases (e.g. rheumatoid arthritis, osteoarthritis, gout, ankylosing spondylitis or musculoskeletal disorders).

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NAPROXEN TABLETS

Do not take Naproxen Gastro-resistant tablets

- If you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- If you are allergic to other NSAIDs (e.g. ibuprofen, aspirin)
- If you have or have had a serious heart condition
- If you are in the last three months of your pregnancy
- If you have or have had repeated ulcers or bleeding in the stomach or intestines
- If you have or have had problems with your liver or kidneys.

##### Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if you

- are planning a pregnancy or are having problems becoming pregnant, as this medicine may make it more difficult to become pregnant
- are elderly, have ulcerative colitis or Crohn's disease, as there is a higher risk of stomach problems (e.g. ulcers or bleeding)
- have blood clotting problems or are taking medicines to stop your blood clotting
- have asthma, other breathing problems, lumps in your nose (polyps) or have had a skin rash, facial swelling or a blocked or runny nose after taking another NSAID
- have been told that you have Systemic Lupus Erythematosus (a condition where your immune system attacks itself).

Medicines such as Naproxen Gastro-resistant tablets may be linked to a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood

pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

##### Children

Do not give this medicine to children under 5 years old.

##### Other medicines and Naproxen Tablets

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how this medicine works:

- Aspirin or other NSAIDs for pain and swelling or Probenecid to treat gout
- Methotrexate to treat cancer
- Medicines to stop your blood clotting such as warfarin
- Medicines for high blood pressure or heart failure
- Diuretics (water tablets) like furosemide
- Medicines to suppress the immune system such as Tacrolimus or steroid hormones
- Medicines called Sulphonamides or Quinolone antibiotics to treat bacterial infections
- Zidovudine to treat viral infections
- Digoxin to treat heart failure
- Lithium for mental health problems
- Medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs) for depression
- Phenytoin for epilepsy
- Medicines to increase urine production
- Mifepristone for abortion
- Bisphosphonates
- Colestyramine.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Naproxen Gastro-resistant tablets.

##### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

##### Pregnancy

Do not take this medicine if you are in the last three months of your pregnancy. Avoid these tablets if you are in first six months of your pregnancy.

##### Breast-feeding

If you are breast-feeding unless your doctor has advised you to take them.

##### Fertility

Naproxen may make it more difficult to become pregnant.

##### Driving and using machines

Naproxen Gastro-resistant tablets may cause dizziness, drowsiness, tiredness, problems with your vision, depressed or difficulty sleeping. If affected do not drive or operate machinery.

##### Naproxen Gastro-resistant tablets contains lactose

If you know you have an intolerance to lactose contact your doctor before taking this medicine.

#### 3. HOW TO TAKE NAPROXEN TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not crush or chew the tablets.

Swallow them whole with a glass of water.

##### Dosage

Your doctor will decide your dose, as it depends on your condition.

The recommended dose is:

##### Adults:

**Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis** - Typical dose is 500-1000 mg daily, taken in two divided doses at 12 hour intervals. If 1 g is needed this can be given as two 500mg doses or as a single dose.

**Severe night-time pain and morning stiffness** - Typical dose is 750-1000 mg per day.

**Gout** - Typical dose is 750 mg, then 250 mg every 6 - 8 hours until the attack has passed.

**Musculoskeletal disorders and period pain** - Typical dose is 500 mg then 250 mg every 6 - 8 hours. Maximum daily dose is 1250 mg.

#### **Elderly and patients with liver and kidney problems:**

Require smaller doses. Follow your doctor's advice.

Children over 5 years of age:

**Juvenile rheumatoid arthritis** - The usual dose is 10 mg/kg bodyweight a day, split into two doses at 12 hour intervals. Naproxen tablets should not be used in children under 16 years of age for any other condition.

#### **If you take more Naproxen Gastro-resistant tablets than you should**

Contact your doctor or pharmacist immediately. Show them the package.

#### **If you forget to take Naproxen Gastro-resistant tablets**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following serious side effects STOP TAKING Naproxen and tell your doctor immediately or go to the nearest hospital emergency department:**

**Serious stomach or gut problems**, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut sometimes fatal particularly in elderly. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

**Allergic reactions** which may cause asthma, difficulty breathing, swelling of throat, face, hands or feet, skin rashes, blisters or itching.

**Severe skin rashes** signs include blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.

**Liver problems** signs include yellowing of your skin or the whites of your eyes (jaundice).

Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

**Heart attack** signs include chest pain which may spread to your neck and shoulders and down your left arm.

**Stroke** signs include muscle weakness and numbness. This may only be on one side of your body. A suddenly altered sense of smell, taste, hearing or vision, confusion.

**Meningitis** signs include fever, feeling or being sick, a stiff neck, headache, depression, vertigo, drowsiness, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

#### **Other possible side effects**

##### **Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

##### **Blood**

- Blood problems, like anaemia or changes to the numbers of white blood cells.

##### **Mental illness**

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion or seeing and possibly hearing things that are not there (hallucinations).

##### **Nervous system**

- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

##### **Eyes and ears**

- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.

- Dizziness that causes problems with your balance.

##### **Heart and circulation**

- Swelling of your hands, feet or legs (oedema), this may be with chest pains, tiredness, shortness of breath (cardiac failure).
- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

##### **Chest**

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

##### **Skin and hair**

- Skin rashes including redness, hives, pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

##### **Urinary**

- Blood in your water (urine) or kidney problems.

##### **Other**

Thirst, fever, feeling tired or generally unwell, a sore mouth or mouth ulcers, problems for women in getting pregnant, 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

##### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE NAPROXEN TABLETS**

**Keep this medicine out of the sight and reach of children.**

Do not store above 25°C. Store in the original container and keep the container tightly closed.

Do not use this medicine after the expiry date, which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What Naproxen Gastro-resistant tablets contains**

The active ingredient in this medicine is naproxen. The other ingredients are lactose, potato starch, povidone, glycerol, sodium starch glycollate, magnesium stearate, eudragit L 12.5 and L30D, triacetin, talc, polyethylene glycol and simethicone emulsion.

#### **What Naproxen Gastro-resistant tablets looks like and contents of the pack**

Naproxen 250 mg Gastro-resistant tablets are oval white tablets with no markings. Naproxen 500 mg Gastro-resistant tablets are oblong white tablets with a break line engraved on one side.

The tablets come in blisters packs and containers of 8, 20, 56, 60, 84, 100 and 250 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Chelonia Healthcare Limited,  
11 Boumpoulinas, Nicosia, P.C. 1060, Cyprus

#### **Manufacturer**

Haupt Pharma Berlin GmbH,  
Moosrosenstrasse 7, 12347 Berlin, Germany

For more information about this product, please contact the Marketing Authorisation Holder.

**This leaflet was last amended in 06/2017**

CL0144-0145/O/PIL1/CL3

PACKAGE LEAFLET: INFORMATION FOR THE USER

# NAPROXEN

## 250 mg & 500 mg

### GASTRO-RESISTANT TABLETS

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- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### WHAT IS IN THIS LEAFLET

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#### 1. WHAT NAPROXEN TABLETS IS AND WHAT IT IS USED FOR

Naproxen is a Non-Steroidal Anti-Inflammatory Drug (NSAID) used to reduce pain and swelling in joint, bone or muscle diseases (e.g. rheumatoid arthritis, osteoarthritis, gout, ankylosing spondylitis or musculoskeletal disorders).

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NAPROXEN TABLETS

Do not take Naproxen Gastro-resistant tablets

- If you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- If you are allergic to other NSAIDs (e.g. ibuprofen, aspirin)
- If you have or have had a serious heart condition
- If you are in the last three months of your pregnancy
- If you have or have had repeated ulcers or bleeding in the stomach or intestines
- If you have or have had problems with your liver or kidneys.

##### Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if you

- are planning a pregnancy or are having problems becoming pregnant, as this medicine may make it more difficult to become pregnant
- are elderly, have ulcerative colitis or Crohn's disease, as there is a higher risk of stomach problems (e.g. ulcers or bleeding)
- have blood clotting problems or are taking medicines to stop your blood clotting
- have asthma, other breathing problems, lumps in your nose (polyps) or have had a skin rash, facial swelling or a blocked or runny nose after taking another NSAID
- have been told that you have Systemic Lupus Erythematosus (a condition where your immune system attacks itself).

Medicines such as Naproxen Gastro-resistant tablets may be linked to a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood

pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

##### Children

Do not give this medicine to children under 5 years old.

##### Other medicines and Naproxen Tablets

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how this medicine works:

- Aspirin or other NSAIDs for pain and swelling or Probenecid to treat gout
- Methotrexate to treat cancer
- Medicines to stop your blood clotting such as warfarin
- Medicines for high blood pressure or heart failure
- Diuretics (water tablets) like furosemide
- Medicines to suppress the immune system such as Tacrolimus or steroid hormones
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- Digoxin to treat heart failure
- Lithium for mental health problems
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- Phenytoin for epilepsy
- Medicines to increase urine production
- Mifepristone for abortion
- Bisphosphonates
- Colestyramine.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Naproxen Gastro-resistant tablets.

##### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

##### Pregnancy

Do not take this medicine if you are in the last three months of your pregnancy. Avoid these tablets if you are in first six months of your pregnancy.

##### Breast-feeding

If you are breast-feeding unless your doctor has advised you to take them.

##### Fertility

Naproxen may make it more difficult to become pregnant.

##### Driving and using machines

Naproxen Gastro-resistant tablets may cause dizziness, drowsiness, tiredness, problems with your vision, depressed or difficulty sleeping. If affected do not drive or operate machinery.

##### Naproxen Gastro-resistant tablets contains lactose

If you know you have an intolerance to lactose contact your doctor before taking this medicine.

#### 3. HOW TO TAKE NAPROXEN TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not crush or chew the tablets.

Swallow them whole with a glass of water.

##### Dosage

Your doctor will decide your dose, as it depends on your condition.

The recommended dose is:

##### Adults:

**Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis** - Typical dose is 500-1000 mg daily, taken in two divided doses at 12 hour intervals. If 1 g is needed this can be given as two 500mg doses or as a single dose.

**Severe night-time pain and morning stiffness** - Typical dose is 750-1000 mg per day.

**Gout** - Typical dose is 750 mg, then 250 mg every 6 - 8 hours until the attack has passed.

**Musculoskeletal disorders and period pain** - Typical dose is 500 mg then 250 mg every 6 - 8 hours. Maximum daily dose is 1250 mg.

#### **Elderly and patients with liver and kidney problems:**

Require smaller doses. Follow your doctor's advice.

Children over 5 years of age:

**Juvenile rheumatoid arthritis** - The usual dose is 10 mg/kg bodyweight a day, split into two doses at 12 hour intervals. Naproxen tablets should not be used in children under 16 years of age for any other condition.

#### **If you take more Naproxen Gastro-resistant tablets than you should**

Contact your doctor or pharmacist immediately. Show them the package.

#### **If you forget to take Naproxen Gastro-resistant tablets**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following serious side effects STOP TAKING Naproxen and tell your doctor immediately or go to the nearest hospital emergency department:**

#### **Serious stomach or gut problems**, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut sometimes fatal particularly in elderly. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

**Allergic reactions** which may cause asthma, difficulty breathing, swelling of throat, face, hands or feet, skin rashes, blisters or itching.

**Severe skin rashes** signs include blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.

**Liver problems** signs include yellowing of your skin or the whites of your eyes (jaundice).

Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

**Heart attack** signs include chest pain which may spread to your neck and shoulders and down your left arm.

**Stroke** signs include muscle weakness and numbness. This may only be on one side of your body. A suddenly altered sense of smell, taste, hearing or vision, confusion.

**Meningitis** signs include fever, feeling or being sick, a stiff neck, headache, depression, vertigo, drowsiness, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

#### **Other possible side effects**

##### **Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

##### **Blood**

- Blood problems, like anaemia or changes to the numbers of white blood cells.

##### **Mental illness**

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion or seeing and possibly hearing things that are not there (hallucinations).

##### **Nervous system**

- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

##### **Eyes and ears**

- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.

- Dizziness that causes problems with your balance.

##### **Heart and circulation**

- Swelling of your hands, feet or legs (oedema), this may be with chest pains, tiredness, shortness of breath (cardiac failure).
- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

##### **Chest**

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

##### **Skin and hair**

- Skin rashes including redness, hives, pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

##### **Urinary**

- Blood in your water (urine) or kidney problems.

##### **Other**

Thirst, fever, feeling tired or generally unwell, a sore mouth or mouth ulcers, problems for women in getting pregnant, 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE NAPROXEN TABLETS**

#### **Keep this medicine out of the sight and reach of children.**

Do not store above 25°C. Store in the original container and keep the container tightly closed.

Do not use this medicine after the expiry date, which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What Naproxen Gastro-resistant tablets contains**

The active ingredient in this medicine is naproxen. The other ingredients are lactose, potato starch, povidone, glycerol, sodium starch glycollate, magnesium stearate, eudragit L 12.5 and L30D, triacetin, talc, polyethylene glycol and simethicone emulsion.

#### **What Naproxen Gastro-resistant tablets looks like and contents of the pack**

Naproxen 250 mg Gastro-resistant tablets are oval white tablets with no markings. Naproxen 500 mg Gastro-resistant tablets are oblong white tablets with a break line engraved on one side.

The tablets come in blisters packs and containers of 8, 20, 56, 60, 84, 100 and 250 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Chelonia Healthcare Limited,  
11 Boumpoulinas, Nicosia, P.C. 1060, Cyprus

#### **Manufacturer**

DDSA Pharmaceuticals Limited,  
84 Pembroke Road, London, W8 6NX, UK

For more information about this product, please contact the Marketing Authorisation Holder.

This leaflet was last amended in 06/2017

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PACKAGE LEAFLET: INFORMATION FOR THE USER

# ARTHROSIN EC

## 250 mg & 500 mg

### GASTRO-RESISTANT TABLETS

#### Naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### WHAT IS IN THIS LEAFLET

1. What Arthrosin EC Tablets is and what it is used for
2. What you need to know before you take Arthrosin EC Tablets
3. How to take Arthrosin EC Tablets
4. Possible side effects
5. How to store Arthrosin EC Tablets
6. Contents of the pack and other information

#### 1. WHAT ARTHROSIN EC TABLETS IS AND WHAT IT IS USED FOR

Arthrosin EC is a Non-Steroidal Anti-Inflammatory Drug (NSAID) used to reduce pain and swelling in joint, bone or muscle diseases (e.g. rheumatoid arthritis, osteoarthritis, gout, ankylosing spondylitis or musculoskeletal disorders).

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARTHROSIN EC TABLETS

Do not take Arthrosin EC Gastro-resistant tablets

- If you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- If you are allergic to other NSAIDs (e.g. ibuprofen, aspirin)
- If you have or have had a serious heart condition
- If you are in the last three months of your pregnancy
- If you have or have had repeated ulcers or bleeding in the stomach or intestines
- If you have or have had problems with your liver or kidneys.

#### Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if you

- are planning a pregnancy or are having problems becoming pregnant, as this medicine may make it more difficult to become pregnant
- are elderly, have ulcerative colitis or Crohn's disease, as there is a higher risk of stomach problems (e.g. ulcers or bleeding)
- have blood clotting problems or are taking medicines to stop your blood clotting
- have asthma, other breathing problems, lumps in your nose (polyps) or have had a skin rash, facial swelling or a blocked or runny nose after taking another NSAID
- have been told that you have Systemic Lupus Erythematosus (a condition where your immune system attacks itself).

Medicines such as Arthrosin EC Gastro-resistant tablets may be linked to a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

#### Children

Do not give this medicine to children under 5 years old.

#### Other medicines and Arthrosin EC Tablets

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how this medicine works:

- Aspirin or other NSAIDs for pain and swelling or Probenecid to treat gout
- Methotrexate to treat cancer
- Medicines to stop your blood clotting such as warfarin
- Medicines for high blood pressure or heart failure
- Diuretics (water tablets) like furosemide
- Medicines to suppress the immune system such as Tacrolimus or steroid hormones
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- Zidovudine to treat viral infections
- Digoxin to treat heart failure
- Lithium for mental health problems
- Medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs) for depression
- Phenytoin for epilepsy
- Medicines to increase urine production
- Mifepristone for abortion
- Bisphosphonates
- Colestyramine.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Arthrosin EC Gastro-resistant tablets.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

Do not take this medicine if you are in the last three months of your pregnancy. Avoid these tablets if you are in first six months of your pregnancy.

#### Breast-feeding

If you are breast-feeding unless your doctor has advised you to take them.

#### Fertility

Arthrosin EC may make it more difficult to become pregnant.

#### Driving and using machines

Arthrosin EC Gastro-resistant tablets may cause dizziness, drowsiness, tiredness, problems with your vision, depressed or difficulty sleeping. If affected do not drive or operate machinery.

#### Arthrosin EC Gastro-resistant tablets contains lactose

If you know you have an intolerance to lactose contact your doctor before taking this medicine.

#### 3. HOW TO TAKE ARTHROSIN EC TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not crush or chew the tablets.

Swallow them whole with a glass of water.

#### Dosage

Your doctor will decide your dose, as it depends on your condition.

#### The recommended dose is:

#### Adults:

**Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis** - Typical dose is 500-1000 mg daily, taken in two divided doses at 12 hour intervals. If 1 g is needed this can be given as two 500mg doses or as a single dose.

**Severe night-time pain and morning stiffness** - Typical dose is 750-1000 mg per day.

**Gout** - Typical dose is 750 mg, then 250 mg every 6 - 8 hours until the attack has passed.

**Musculoskeletal disorders and period pain** - Typical dose is 500 mg then 250 mg every 6 - 8 hours. Maximum daily dose is 1250 mg.

**Elderly and patients with liver and kidney problems:** Require smaller doses. Follow your doctor's advice.

Children over 5 years of age:

**Juvenile rheumatoid arthritis** - The usual dose is 10 mg/kg bodyweight a day, split into two doses at 12 hour intervals. Arthrosin EC tablets should not be used in children under 16 years of age for any other condition.

**If you take more Arthrosin EC Gastro-resistant tablets than you should**

Contact your doctor or pharmacist immediately. Show them the package.

**If you forget to take Arthrosin EC Gastro-resistant tablets**  
Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten dose.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following serious side effects STOP TAKING Arthrosin EC and tell your doctor immediately or go to the nearest hospital emergency department:**

**Serious stomach or gut problems**, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut sometimes fatal particularly in elderly. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

**Allergic reactions** which may cause asthma, difficulty breathing, swelling of throat, face, hands or feet, skin rashes, blisters or itching

**Severe skin rashes** signs include blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.

**Liver problems** signs include yellowing of your skin or the whites of your eyes (jaundice).

Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

**Heart attack** signs include chest pain which may spread to your neck and shoulders and down your left arm.

**Stroke** signs include muscle weakness and numbness. This may only be on one side of your body. A suddenly altered sense of smell, taste, hearing or vision, confusion.

**Meningitis** signs include fever, feeling or being sick, a stiff neck, headache, depression, vertigo, drowsiness, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

**Other possible side effects**

**Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

**Blood**

- Blood problems, like anaemia or changes to the numbers of white blood cells.

**Mental illness**

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion or seeing and possibly hearing things that are not there (hallucinations).

**Nervous system**

- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

**Eyes and ears**

- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.
- Dizziness that causes problems with your balance.

**Heart and circulation**

- Swelling of your hands, feet or legs (oedema), this may be with chest pains, tiredness, shortness of breath (cardiac failure).

- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

**Chest**

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

**Skin and hair**

- Skin rashes including redness, hives, pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

**Urinary**

- Blood in your water (urine) or kidney problems.

**Other**

Thirst, fever, feeling tired or generally unwell, a sore mouth or mouth ulcers, problems for women in getting pregnant, 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE ARTHROSIN EC TABLETS

**Keep this medicine out of the sight and reach of children.**

Do not store above 25°C. Store in the original container and keep the container tightly closed.

Do not use this medicine after the expiry date, which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Arthrosin EC Gastro-resistant tablets contains**

The active ingredient in this medicine is naproxen. The other ingredients are lactose, potato starch, povidone, glycerol, sodium starch glycolate, magnesium stearate, eudragit L 12.5 and L30D, triacetin, talc, polyethylene glycol and simethicone emulsion.

**What Arthrosin EC Gastro-resistant tablets looks like and contents of the pack**

Arthrosin EC 250 mg Gastro-resistant tablets are oval white tablets with no markings. Arthrosin EC 500 mg Gastro-resistant tablets are oblong white tablets with a break line engraved on one side.

The tablets come in blisters packs and containers of 8, 20, 56, 60, 84, 100 and 250 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Chelonia Healthcare Limited,  
11 Boumpoulinas, Nicosia, P.C. 1060, Cyprus

**Manufacturer**

Haupt Pharma Berlin GmbH,  
Moosrosenstrasse 7, 12347 Berlin, Germany

DDSA Pharmaceuticals Limited,  
84 Pembroke Road, London, W8 6NX, UK

For more information about this product, please contact the Marketing Authorisation Holder.

**This leaflet was last amended in 06/2017**

CL0144-0145/O/PIL1-Br1/CL3  
CL0144-0145/O/PIL2-Br1/CL3

PACKAGE LEAFLET: INFORMATION FOR THE USER

# NYCOPREN

## 250 mg & 500 mg

### GASTRO-RESISTANT TABLETS

#### Naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### WHAT IS IN THIS LEAFLET

1. What Nycopren Tablets is and what it is used for
2. What you need to know before you take Nycopren Tablets
3. How to take Nycopren Tablets
4. Possible side effects
5. How to store Nycopren Tablets
6. Contents of the pack and other information

#### 1. WHAT NYCOPREN TABLETS IS AND WHAT IT IS USED FOR

Nycopren is a Non-Steroidal Anti-Inflammatory Drug (NSAID) used to reduce pain and swelling in joint, bone or muscle diseases (e.g. rheumatoid arthritis, osteoarthritis, gout, ankylosing spondylitis or musculoskeletal disorders).

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NYCOPREN TABLETS

Do not take Nycopren Gastro-resistant tablets

- If you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- If you are allergic to other NSAIDs (e.g. ibuprofen, aspirin)
- If you have or have had a serious heart condition
- If you are in the last three months of your pregnancy
- If you have or have had repeated ulcers or bleeding in the stomach or intestines
- If you have or have had problems with your liver or kidneys.

#### Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if you

- are planning a pregnancy or are having problems becoming pregnant, as this medicine may make it more difficult to become pregnant
- are elderly, have ulcerative colitis or Crohn's disease, as there is a higher risk of stomach problems (e.g. ulcers or bleeding)
- have blood clotting problems or are taking medicines to stop your blood clotting
- have asthma, other breathing problems, lumps in your nose (polyps) or have had a skin rash, facial swelling or a blocked or runny nose after taking another NSAID
- have been told that you have Systemic Lupus Erythematosus (a condition where your immune system attacks itself).

Medicines such as Nycopren Gastro-resistant tablets may be linked to a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

#### Children

Do not give this medicine to children under 5 years old.

#### Other medicines and Nycopren Tablets

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how this medicine works:

- Aspirin or other NSAIDs for pain and swelling or Probenecid to treat gout
- Methotrexate to treat cancer
- Medicines to stop your blood clotting such as warfarin
- Medicines for high blood pressure or heart failure
- Diuretics (water tablets) like furosemide
- Medicines to suppress the immune system such as Tacrolimus or steroid hormones
- Medicines called Sulphonamides or Quinolone antibiotics to treat bacterial infections
- Zidovudine to treat viral infections
- Digoxin to treat heart failure
- Lithium for mental health problems
- Medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs) for depression
- Phenytoin for epilepsy
- Medicines to increase urine production
- Mifepristone for abortion
- Bisphosphonates
- Colestyramine.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Nycopren Gastro-resistant tablets.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

Do not take this medicine if you are in the last three months of your pregnancy. Avoid these tablets if you are in first six months of your pregnancy.

#### Breast-feeding

If you are breast-feeding unless your doctor has advised you to take them.

#### Fertility

Nycopren may make it more difficult to become pregnant.

#### Driving and using machines

Nycopren Gastro-resistant tablets may cause dizziness, drowsiness, tiredness, problems with your vision, depressed or difficulty sleeping. If affected do not drive or operate machinery.

#### Nycopren Gastro-resistant tablets contains lactose

If you know you have an intolerance to lactose contact your doctor before taking this medicine.

#### 3. HOW TO TAKE NYCOPREN TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not crush or chew the tablets.

Swallow them whole with a glass of water.

#### Dosage

Your doctor will decide your dose, as it depends on your condition.

The recommended dose is:

#### Adults:

**Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis** - Typical dose is 500-1000 mg daily, taken in two divided doses at 12 hour intervals. If 1 g is needed this can be given as two 500mg doses or as a single dose.

**Severe night-time pain and morning stiffness** - Typical dose is 750-1000 mg per day.

**Gout** - Typical dose is 750 mg, then 250 mg every 6 - 8 hours until the attack has passed.

**Musculoskeletal disorders and period pain** - Typical dose is 500 mg then 250 mg every 6 - 8 hours. Maximum daily dose is 1250 mg.

#### Elderly and patients with liver and kidney problems:

Require smaller doses. Follow your doctor's advice.

Children over 5 years of age:

**Juvenile rheumatoid arthritis** - The usual dose is 10 mg/kg bodyweight a day, split into two doses at 12 hour intervals. Nycopren tablets should not be used in children under 16 years of age for any other condition.

**If you take more Nycopren Gastro-resistant tablets than you should**

Contact your doctor or pharmacist immediately. Show them the package.

**If you forget to take Nycopren Gastro-resistant tablets**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten dose.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following serious side effects STOP TAKING Nycopren and tell your doctor immediately or go to the nearest hospital emergency department:**

**Serious stomach or gut problems**, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut sometimes fatal particularly in elderly. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

**Allergic reactions** which may cause asthma, difficulty breathing, swelling of throat, face, hands or feet, skin rashes, blisters or itching.

**Severe skin rashes** signs include blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.

**Liver problems** signs include yellowing of your skin or the whites of your eyes (jaundice).

Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

**Heart attack** signs include chest pain which may spread to your neck and shoulders and down your left arm.

**Stroke** signs include muscle weakness and numbness. This may only be on one side of your body. A suddenly altered sense of smell, taste, hearing or vision, confusion.

**Meningitis** signs include fever, feeling or being sick, a stiff neck, headache, depression, vertigo, drowsiness, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

**Other possible side effects**

**Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

**Blood**

- Blood problems, like anaemia or changes to the numbers of white blood cells.

**Mental illness**

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
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**Nervous system**

- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

**Eyes and ears**

- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.
- Dizziness that causes problems with your balance.

**Heart and circulation**

- Swelling of your hands, feet or legs (oedema), this may be with chest pains, tiredness, shortness of breath (cardiac failure).

- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

**Chest**

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

**Skin and hair**

- Skin rashes including redness, hives, pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

**Urinary**

- Blood in your water (urine) or kidney problems.

**Other**

Thirst, fever, feeling tired or generally unwell, a sore mouth or mouth ulcers, problems for women in getting pregnant, 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

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