

## Package leaflet: Information for the patient

### Stirlescent 250 mg Effervescent 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. Do not pass it on to others. It may harm them even if their symptoms 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 Stirlescent 250 mg Effervescent Tablets is and what it is used for
2. What you need to know before you take Stirlescent 250 mg Effervescent Tablets
3. How to take Stirlescent 250 mg Effervescent Tablets
4. Possible side effects
5. How to store Stirlescent 250 mg Effervescent Tablets
6. Contents of the pack and other information

#### **1. What Stirlescent 250 mg Effervescent Tablets is and what it is used for**

Stirlescent 250 mg Effervescent Tablets contains the drug naproxen. This is a 'Non Steroidal Anti Inflammatory Drug' or NSAID.

Stirlescent 250 mg Effervescent Tablets can lessen pain and inflammation (swelling, redness and heat) and is used to treat adults for:

- Pain in your muscles, joints and tendons, like strains, gout, arthritis and ankylosing spondylitis.
- Period pain.

#### **2. What you need to know before you take Stirlescent 250 mg Effervescent Tablets**

##### **Do not take Stirlescent 250 mg Effervescent Tablets**

- If you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to aspirin, other NSAIDs or any other pain relief medicines (such as ibuprofen or diclofenac).
- If you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- If you have previously experienced bleeding or perforation in your stomach while taking NSAIDs.
- If you have **severe** problems with your kidneys, liver or heart.
- If you are in the last three months of pregnancy.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

If you suffer from any of the following at any time during your treatment, STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your stools (faeces/motions).
- Pass black, tarry stools.
- Vomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heartburn.
- Pains in your stomach or other abnormal stomach symptoms.

### **Warnings and precautions**

#### **Take special care with Stirlescent 250 mg Effervescent Tablets**

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

Check with your doctor or pharmacist before taking this medicine if you have any of the following:

- Asthma or allergies (like hay fever).
- Previous swelling of the face, lips, eyes or tongue.
- A feeling of weakness (perhaps because of an illness) or you are elderly.
- Lumps in your nose (polyps), or if you sneeze a lot or have a runny, blocked or itchy nose.
- Other problems with your kidneys or liver.
- An autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).
- Your blood does not clot normally.
- Too much fat in your blood (hyperlipidaemia).
- Problems with the blood vessels (arteries) anywhere in your body.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take this medicine.

### **Children and adolescents**

This medicine should not be used by children and adolescents under 18 years of age.

### **Other medicines and Stirlescent 250 mg Effervescent Tablets**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. In particular, tell your doctor or pharmacist if you are taking:

- Other pain killers, like ibuprofen, diclofenac and paracetamol.
- Medicine to stop your blood clotting such as aspirin/acetylsalicylic acid, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy), like phenytoin.
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections).
- A sulfonylurea (for diabetes), like glimepiride or glipizide.
- An 'ACE inhibitor' or any other medicine for high blood pressure like cilazapril, enalapril or propranolol.
- An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan (for treating high blood pressure).
- A diuretic (water tablet) (for high blood pressure), like furosemide.
- A 'cardiac glycoside' (for heart problems), like digoxin.
- A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems like lithium or 'SSRIs' like fluoxetine or citalopram.
- Probenecid (for gout).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin or tacrolimus (for skin problems or after an organ transplant).
- Zidovudine (used to treat AIDS and HIV infections).
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died).

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take this medicine.

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

- **DO NOT TAKE** this medicine if you are in the last three months of pregnancy, as it can harm your baby.
- Talk to your doctor **BEFORE** taking this medicine if you are in the first six months of pregnancy, think you are pregnant, plan to get pregnant or are breast-feeding. Your doctor will decide if you should take this medicine.
- This medicine may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

### **Driving and using machines**

This medicine can make you tired, drowsy or dizzy, and could make you depressed or confused. It may also cause problems with your eyesight and balance. Talk to your doctor if any of these happen to you and, if affected, do not drive or use any tools or machines.

### **Stirlescent 250 mg Effervescent Tablets contain sodium**

Each Stirlescent 250 mg Effervescent Tablet contains 342 mg of sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 17.1% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 2 or more effervescent tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

## **3. How to take Stirlescent 250 mg Effervescent Tablets**

Medicines containing naproxen may be linked with a small increased risk of heart attack or stroke. Any risk is more likely with higher doses and prolonged (longer term) treatment. **Do not exceed the recommended dose or length of your treatment.** Check with your doctor if you are not sure.

Dissolve 1 to 2 tablets in a glass (150 ml) of water and drink, doses of 3 tablets should be dissolved in 300 ml. To make sure there is no medicine left, rinse the empty glass with a small amount (10 ml) of water and drink it. Take with or after food.

Make sure that you have enough to drink and stay well hydrated when taking this medicine.

This is particularly important for people who have problems with their kidneys.

While you are taking this medicine, your doctor will want to see you to check you are on the right dose for you and look for any side effects. This is particularly important if you are elderly.

### **The recommended dose for adults**

#### **Muscle, joint or tendon pain and period pain**

- The usual starting dose is 2 tablets, followed by a tablet every 6 to 8 hours as needed.

#### **Arthritis and ankylosing spondylitis**

- The usual dose is between 2 to 4 tablets
- The dose should be split in two and taken twice a day.

#### **Gout**

- The usual starting dose is 3 tablets, followed by a tablet every 8 hours as needed.

### **Use in children**

Stirlescent 250 mg Effervescent Tablets are not for use in children under 18 years of age.

### **The elderly and people with liver and kidney problems**

Your doctor will decide your dose, it will usually be lower than that for other adults.

### **If you take more Stirlescent 250 mg Effervescent Tablets than you should**

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

### **If you forget to take Stirlescent 250 mg Effervescent Tablets**

If you forget to take a dose, skip the missed dose and then take your next dose as normal. Do not take a double dose to make up for a forgotten dose.

## **4. Possible side effects**

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

Medicines containing naproxen may be associated with a small increased risk of heart attack or stroke.

### **Important side effects to look out for:**

**Stop taking this medicine and tell a doctor straight away if any of the following side effects happen. You may need urgent medical treatment.**

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

- Blood in your vomit, or bits that look like coffee grounds.
- Black sticky bowel motions (stools) or bloody diarrhoea.
- 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**, signs include:

- Sudden swelling of your throat, face, hands or feet.
- Difficulty breathing, tightness in your chest.
- Skin rashes, blisters or itching.

**Severe skin rashes**, signs include:

- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time.
- Blistering of skin when exposed to sunlight, mostly seen on the 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 and tightening 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, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

If you notice any of the serious side effects mentioned above, stop taking this medicine and tell your doctor straight away.

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

#### **Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind, difficult and/or painful swallowing, a feeling of something of being stuck in the throat.

#### **Blood**

- Blood problems, like anaemia or changes to the numbers of white blood cells.
- High levels of potassium in the blood (hyperkalaemia).

#### **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. This may be with chest pains, tiredness or 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.
- Muscle pain or weakness.
- Problems for women in getting pregnant.
- ‘Systemic lupus erythematosus’ (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

#### **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 directly via:

<b>Ireland</b>	<b>Malta</b>	<b>United Kingdom</b>
HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: <a href="http://www.hpra.ie">www.hpra.ie</a> e-mail: <a href="mailto:medsafety@hpra.ie">medsafety@hpra.ie</a>	ADR Reporting Website: <a href="http://www.medicinesauthority.gov.mt/adrportal">www.medicinesauthority.gov.mt/adrportal</a>	Yellow Card Scheme Website: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Stirlescent 250 mg Effervescent Tablets**

This medicine does not require any special storage conditions.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. 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 protect the environment.

## **6. Contents of the pack and other information**

### **What Stirlescent 250 mg Effervescent Tablets contains**

The active substance in this medicine is naproxen. Each tablet contains 250 mg (milligrams) of naproxen. Each tablet also contains 342 mg sodium.

The other ingredients in the tablets are citric acid, sodium hydrogen carbonate, sodium carbonate, sodium cyclamate, saccharin sodium, sodium citrate, povidone, macrogol 6000, mannitol (E421), simeticone, docusate sodium, blackcurrant flavour.

### **What Stirlescent 250 mg Effervescent Tablets looks like and contents of the pack**

Stirlescent 250 mg Effervescent Tablets are large, round, white tablets.

The tablets are supplied in plastic tubes or aluminium paper foil containing 10, 12, 15, 20, 24 or 30 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Stirling Anglian Pharmaceuticals Ltd.

Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU, United Kingdom

#### **Manufacturer**

HERMES ARZNEIMITTEL GmbH,

Georg-Kalb-Strasse 5-8,

82049 Grohesselohe/Munich,

Germany

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland                      Stirlescent 250 mg Effervescent Tablets

Malta                         Stirlescent 250 mg Effervescent Tablets

UK                             Stirlescent 250 mg Effervescent Tablets

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