

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:

- relieve problems with your muscles, joints and tendons e.g. strains, back pain, ankylosing spondylitis (pain and stiffness in the neck and back), gout, rheumatoid arthritis or osteoarthritis.
- relieve period pain.

Stirlescent 250 mg Effervescent Tablets are used to treat adults only.

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.

Warnings and precautions

Medicines such as Stirlescent 250 mg Effervescent Tablets may be associated (linked) with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with longer term treatment. **Do not exceed (take more than) the recommended dose or duration (length) of treatment.**

Talk to your doctor or pharmacist before taking Stirlescent 250mg Effervescent Tablets if you:

- have heart problems, had a previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- have asthma or allergies (like hay fever) or have had swelling of the face, lips, eyes or tongue in the past.
- have or had a history of a stomach ulcer, stomach bleeding or other stomach problems.
- have a feeling of weakness (perhaps because of an illness).
- are elderly as you have a higher risk of getting side effects when taking NSAIDs particularly stomach ulcers or bleeding which may be fatal.
- have or had in the past lumps in your nose (polyps) or if you sneeze a lot or have a runny, blocked or itchy nose (rhinitis).
- have problems with your kidneys. The signs include feeling tired, bruising easily and passing water (urinating) less often.
- have problems with your liver such as jaundice (yellowing of your skin or the whites of your eyes) or hepatitis (feeling tired, loss of appetite, feeling or being sick and pale coloured stools).
- have an autoimmune condition, such as systemic lupus erythematosus (SLE, causes joint pain, skin rashes and fever) and ulcerative colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).
- have problems with the way your blood clots.
- have too much fat (lipid) in your blood (hyperlipidaemia).
- have 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, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is important as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other pain killers e.g. aspirin, ibuprofen, diclofenac and paracetamol.
- Medicine to stop your blood clotting e.g. aspirin/acetylsalicylic acid, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy) e.g. phenytoin.
- Sulphonamide medicines e.g. hydrochlorothiazide, acetazolamide, indapamide and including sulphonamide antibiotics (for infections).
- A sulphonylurea (for diabetes) e.g. glimepiride or glipizide.
- An ACE inhibitor or any other medicine for high blood pressure e.g. cilazapril, enalapril or propranolol.
- An angiotensin-II receptor antagonist e.g. candesartan, eprosartan or losartan (for treating high blood pressure).
- A diuretic (water tablet) (for high blood pressure) e.g. furosemide.
- A cardiac glycoside (for heart problems) e.g. digoxin.
- A steroid (for swelling and inflammation) e.g. hydrocortisone, prednisolone and dexamethasone.
- A quinolone antibiotic (for infections) e.g. ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems e.g. lithium or SSRIs e.g. 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 you need to have a blood or urine test tell your doctor you are taking Stirlescent 250 mg Effervescent Tablets. You may need to stop taking the tablets for a short time before the tests as they may affect the results.

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.
- 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. 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, dizzy, have problems with your balance or eyesight, depressed or have difficulty sleeping. 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 benzyl alcohol

This medicine contains 0.52 mg benzyl alcohol in each effervescent tablet. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called metabolic acidosis).

Stirlescent 250 mg Effervescent Tablets contain sodium

This medicine contains 342.01 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.

For most indications, the maximum daily dose of this medicinal product (1000 mg) contains 1368.04 mg sodium (found in table salt). This is equivalent to 68.4% of the adult recommended maximum daily dietary intake for sodium. For acute gout treatment, the maximum daily dose (1250 mg) contains 1710.05 mg sodium (found in table salt). This is equivalent to 85.5% of the adult recommended maximum daily dietary intake for sodium.

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.

Stirlescent 250 mg Effervescent Tablets contain sorbitol (E420)

This medicine contains 0.097 mg sorbitol (E420) in each effervescent tablet.

3. How to take Stirlescent 250 mg Effervescent Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

Adults

Muscle, joint or tendon problems and period pain

- The usual starting dose is 2 tablets (500 mg), followed by 1 tablet (250 mg) every 6 to 8 hours as needed. Up to a maximum of 5 tablets (1250 mg) a day may be taken after the first day.

Arthritis and ankylosing spondylitis

- The usual dose is between 2 to 4 tablets (500 mg to 1000 mg).
- The dose should be split in two and taken at 12-hour intervals.

Gout

- The usual starting dose is 3 tablets (750 mg), followed by 1 tablet (250 mg) every 8 hours until the attack has passed.

Use in children and adolescents

Stirlescent 250 mg Effervescent Tablets are not for use in children or adolescents 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 such as Stirlescent 250 mg Effervescent Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you are elderly you have a higher risk of getting side effects when taking NSAIDs particularly stomach ulcers or bleeding which may be fatal.

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:

- 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 black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. 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.
- Narrowing and/or blockage of the gut. Signs include swollen abdomen, stomach pain and vomiting.

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.

- Skin blistering 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 (inflammation of the liver (hepatitis) which can be fatal).
- Changes in how well your liver is working (shown by 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.

Blood

- Blood problems, like anaemia or changes to the numbers of white blood cells.
- A severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis).

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 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.

Kidney and urinary

- Blood in your water (urine) or kidney problems.
- Decrease/increase in the amount of water you pass.
- Protein in your water (shown in tests).

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.
- High levels of potassium in the blood (hyperkalaemia), shown in blood tests. Signs include feeling sick, feeling tired, irregular heartbeat, a slow or weak pulse.

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:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard 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

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.

This medicine does not require any special storage conditions.

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*.

*blackcurrant flavour contains benzyl alcohol and sorbitol (E420)

This medicinal product contains benzyl alcohol, sodium and sorbitol (E420). See section 2 ‘Stirlescent 250 mg Effervescent Tablets contain benzyl alcohol/sodium/sorbitol (E420)’.

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

UK: Marketing Authorisation Holder:

Stirling Anglian Pharmaceuticals Ltd,
Hillington Park Innovation Centre, 1 Ainslie Road,
Hillington Park, Glasgow G52 4RU, UK

EU: Marketing Authorisation Holder:

Stirling Anglian Pharmaceuticals Ireland Ltd,
3 Burlington Road, Dublin 4 D04RD68, Ireland

Manufacturer:

HERMES PHARMA GmbH,
Georg-Kalb-Straße 5,
82049 Pullach i. Isartal
Germany

This medicinal product is authorised in the UK and 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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