

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Secloclin 400 mg Soft Capsules** Contains ibuprofen

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

This medicine is available without prescription, for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use your medicine carefully to get the best results. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, or if any of the side effects gets serious, please tell your doctor or pharmacist. This includes any possible side effects, not listed in this leaflet. See section 4.
- You must see a doctor if your symptoms worsen or persist. See section 3.

#### **What is in this leaflet:**

1. What Secloclin 400 mg Soft Capsules is and what it is used for
2. What you need to know before you take Secloclin 400 mg Soft Capsules
3. How to take Secloclin 400 mg Soft Capsules
4. Possible side effects
5. How to store Secloclin 400 mg Soft Capsules
6. Contents of the pack and other information

### **1. WHAT SECLODIN 400 MG SOFT CAPSULES IS AND WHAT IT IS USED FOR**

Each liquid-filled capsule contains 400 mg of ibuprofen.

Ibuprofen belongs to a group of medicines called NonSteroidal Anti-inflammatory Drugs (NSAIDs) that work by relieving pain and reducing inflammation, swelling and fever.

Secloclin 400 mg Soft Capsules is for the relief of mild to moderate pain including rheumatic and muscular pain, backache, headache, dental pain, period pain, feverishness and the symptoms of colds and influenza. Also for the relief of migraine (with or without aura symptoms e.g. vision disorders, numbness or speech disorders) and the related symptoms such as feeling sick and sensitivity to light and sound.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SECLODIN 400 MG SOFT CAPSULES**

**Please read the following information.**

**Do not give to children under 12 years of age, except on the advice of a doctor.**

#### **Do not take Secloclin 400 mg Soft Capsules if you:**

- are suffering from or have had two or more separate occurrences of stomach ulcers or bleeding.
- have suffered in the past from stomach bleeding or perforation because of treatment with this medicine or any other NSAID.
- suffer from other bleeding conditions or blood disease.
- are allergic to ibuprofen or any of the other ingredients of this product, aspirin, or any other NSAID painkiller.
- suffer from severe liver, kidney or heart failure.
- are in the last 3 months of pregnancy.
- during chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

## **Warnings and Precautions**

### **Talk to your pharmacist or your doctor if you:**

- are asthmatic or suffer from hayfever.
- are suffering from liver or kidney problems.
- are suffering from autoimmune diseases including Systemic Lupus Erythematosus (SLE) – a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorders of other organs.
- are suffering from or have a history of gastro-intestinal disorders, such as ulcerative colitis or Crohn's Disease, because medicines such as ibuprofen may make these conditions worse.
- are in the first 6 months of pregnancy.
- are 12 – 18 years old as there is a risk of renal impairment. Therefore, ask a doctor before use if a child or adolescent between 12-18 years of age has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea.
- have heart problems including heart failure, angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Medicines such as Seclodin 400 mg Soft Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. See section 3.

### **Other medicines and Seclodin 400 mg Soft Capsules**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Do not use this medicine if you are taking aspirin/acetylsalicylic acid with a daily dose above 75 mg, or other NSAID painkillers.

Talk to your doctor or pharmacist if you are taking:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), diuretics (water tablets - increase the amount of urine you produce).
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan), or other medicines, as these may affect or be affected by treatment with ibuprofen.
- other medicines such as corticosteroids (used in the management of asthma and to treat skin diseases and other conditions), anti-platelet agents (generally used to thin the blood to help prevent stroke or heart problems), cardiac glycosides (used in patients with heart problems), selective serotonin reuptake inhibitors (SSRIs) or lithium (used to treat depression), methotrexate (used in the treatment of some cancers, and to treat psoriasis or rheumatoid arthritis), ciclosporin or tacrolimus (used in patients receiving organ transplants, and to treat some skin disorders), zidovudine (used to treat HIV infection), quinoline antibiotics (a class of antibiotics used to treat some infections), phenytoin (used in the treatment of epilepsy) or antacids (used to treat indigestion).

Some other medicines may also affect or be affected by the treatment of Seclodin 400 mg Soft Capsules. You should therefore always seek the advice of a doctor or pharmacist before you take Seclodin 400 mg Soft Capsules with other medicines.

## **Pregnancy and breastfeeding**

Ibuprofen belongs to a group of medicines, NSAIDs, which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before using this medicine if you have problems becoming pregnant or are trying to become pregnant.

If you are in the first 6 months of pregnancy talk to your doctor before taking ibuprofen.

Do not take ibuprofen during the last 3 months of pregnancy.

Ibuprofen appears in breast milk in very low concentrations, but this is unlikely to adversely affect the breast-fed infant.

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.

### **Important information about some of the ingredients of your medicine**

Secloclin 400 mg Soft Capsules contain soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

X 400 mg contains sorbitol (E 420).

Sorbitol is a source of fructose. If your doctor has told you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine

### **3. HOW TO TAKE SECLODIN 400 MG SOFT CAPSULES**

This product is intended for short term use only. You should only take the lowest dose for the shortest time necessary to relieve your symptoms.

If you are aged between 12 and 18 years and the product is required for more than 3 days or if the symptoms worsen, you should contact your doctor.

If you are 18 years or older, you should not take this medicine for longer than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

The recommended dose for

Adults, older people and children and adolescents between 12-18 years of age: 1 capsule up to 3 times a day as required. The recommended interval between doses is approximately 6 to 8 hours, and you must leave at least 4 hours between doses. Do not take more than 3 capsules (1200 mg of ibuprofen) in any 24-hour period. The capsules should be taken with water. Do not chew.

**If you take more Secloclin 400 mg Soft Capsules than you should or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.**

Bring the remaining capsules with you to show the doctor.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

**If you forget to take Secloclin 400 mg Soft Capsules**

Do not take a double dose to make up for a forgotten dose.

If you have questions regarding the use of Seclostin 400 mg Soft Capsules ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

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

The following side effects are very rare (less than 1 in 10,000 people) but if you experience any of these STOP taking this medicine immediately and contact your doctor or pharmacist:

- Stomach ulceration or perforation. Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools.
- Inflammation of the brain lining (meningitis). Symptoms could include stiff neck, headache, feeling or being sick, fever, or feeling disorientated.
- Severe allergic reactions (could be life-threatening). Symptoms may include sudden signs of allergy such as rash, itching or hives on the skin, fainting, low blood pressure, faster heart rate, swelling of the face, tongue and throat, shortness of breath, wheezing or trouble breathing.
- Asthma / worsening of asthma and other breathing difficulties.
- Severe conditions of the skin that may affect the mouth and other parts of the body. This may progress to a severe skin reaction which starts with painful red areas, then large blisters, and ends up with peeling of layers of skin around the mouth, nose, eyes or genitals. This may be accompanied by fever and chills, aching muscles and generally feeling unwell.
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes.

**Medicines such as ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.**

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

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

#### **Less than 1 in 100 people may experience the following uncommon side effects:**

- Allergic reactions such as hives, skin rashes and itching (or Systemic Lupus Erythematosus - SLE).
- Abdominal pain, indigestion, heartburn and feeling sick.
- Headache or dizziness.

#### **Less than 1 in 1,000 people may experience the following rare side effects:**

- Diarrhoea, wind, constipation or being sick.

#### **Less than 1 in 10,000 people may experience the following very rare side effects:**

- Reduction in blood cells, which can make the skin pale or yellow, cause fever, sore throat, mild mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose.
- High blood pressure, heart failure or chest pain. Nervousness, visual impairment, ringing in the ears and dizziness.
- Kidney problems. Symptoms could include swelling of the ankles.
- Severe skin reactions. Symptoms could include blistering.
- Blood in urine, or foamy appearance of urine.

#### **Other very rare side effects with unknown frequency:**

- Worsening of symptoms of colitis and Crohn’s disease. A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of

lymph nodes and an increase of eosinophils (a type of white blood cells).

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE YOUR MEDICINE**

- Do not use this medicine after the expiry date stated on the side of the carton. The expiry date refers to the last day of the month.
- Do not store your medicine above 25°C.
- Keep this medicine out of the sight and reach of children.

Medicines should not be disposed of 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 Seclodin 400 mg Soft Capsules contains**

The active substance is ibuprofen. Each liquid-filled soft capsule contains 400mg of Ibuprofen.

The other ingredients are macrogol 600, potassium hydroxide, partially dehydrated sorbitol liquid (E420), gelatin, purified water, black ink (iron oxide black (E172), propylene glycol, polyvinyl acetate phthalate, macrogol 400, ammonium hydroxide), phosal (soya lecithin, triglycerides (medium chain), glyceryl stearate, oleic acid, ascorbyl palmitate).

### **What Seclodin 400 mg Soft Capsules looks like and contents of the pack**

Seclodin 400 mg Soft Capsules are translucent, oval, soft gelatin capsules printed 'Advil' on one side in black ink.

The blister packs contain 4, 6, 8, 10, 12, 16, 20, 24, 30, 32, 36, 48, 50, 60, 96 or 100 capsules. (Not all pack sizes may be marketed.)

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

The marketing authorisation holder is: Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland

The manufacturer is: Pfizer Consumer Manufacturing Italy S.r.l., Via Nettunense, 90 – 04011 Aprilia (LT), Italy.

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

Ireland – Seclodin 400 mg Soft Capsules

Netherlands – Advil Reliva Forte Liquid Caps, zachte capsules 400mg

United Kingdom – Advil Liquigel 400 mg Capsules

This leaflet was last revised in: December 2019.