

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

### **Oruvail™ 200mg Prolonged Release Capsules, Hard** Ketoprofen

**Is this leaflet hard to see or read? Phone 01 403 5600 for help**

**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).

#### **In this leaflet:**

1. What Oruvail Capsules are and what they are used for
2. What you need to know before you take Oruvail Capsules
3. How to take Oruvail Capsules
4. Possible side effects
5. How to store Oruvail Capsules
6. Contents of the pack and other information

## **1. What Oruvail Capsules are and what they are used for**

### **What Oruvail Capsules are and how they work**

The name of your medicine is Oruvail 200mg Prolonged Release Capsules, Hard (called Oruvail Capsules in this leaflet). Oruvail Capsules contain a medicine called ketoprofen. This belongs to a group of medicines called 'Non-Steroidal Anti-Inflammatory Drugs' (NSAID's). It works by blocking chemicals in your body that normally cause inflammation.

### **What Oruvail Capsules are used for**

Oruvail Capsules are used to treat the swelling, pain, heat, redness and stiffness in your joints and muscles in the following:

- Rheumatoid arthritis (inflammation of your joints)
- Osteoarthritis (where the cushioning (cartilage) between your bone joints is damaged)
- Pain due to problems with your spine
- Lower back pain
- Sprains and strains
- Painful periods
- Pain and inflammation after an operation
- Other painful inflammatory joint, tendon, nerve or muscle problems
- Gout (painful, red, swollen joints)

## **2. What you need to know before you take Oruvail Capsules**

### **Do not take this medicine and tell your doctor if:**

- x You are allergic (hypersensitive) to:
  - ketoprofen
  - aspirin
  - any other Non-Steroidal Anti-Inflammatory Drug (NSAID)
  - any of the other ingredients of Oruvail Capsules (listed in Section 6 below)

- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- x You have or have ever had an ulcer or bleed in your stomach or intestine (gut).
  - x You bruise more easily than usual and have bleeding that lasts a long time.
  - x You have severe heart problems.
  - x You have severe liver or kidney problems.
  - x You have or have ever had blood in your stools or inflammation of your back passage (anus or rectum)
  - x You are pregnant (see 'Pregnancy and breast-feeding' below).

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 using Oruvail Capsules.

### **Warnings and precautions**

#### **Take special care with Oruvail Capsules**

#### **Check with your doctor or pharmacist before taking your medicine if:**

- You are asthmatic.
- You have ulcerative colitis or Crohn's disease.
- You have ever had high blood pressure (hypertension)
- You have an infection – please see heading "Infections" below.
- You have had a stroke
- You have heart problems
- You are 65 years of age or older.
- You are planning a family or trying to conceive

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Oruvail Capsules.

#### **Your doctor may need to keep a close check on you or give you a shorter course of treatment if:**

- You have high cholesterol or blood fats
- You are diabetic
- You smoke
- You have kidney or liver problems
- You are taking water tablets (diuretics)
- You are taking medicines which increase potassium. Your doctor may carry out regular blood tests, particularly for checking the levels of potassium in your blood
- You have heart problems, previously had a stroke or think that you might be at risk of these conditions (if you have high blood pressure, diabetes, high cholesterol or are a smoker)
- You are having or have had heart bypass surgery

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Oruvail Capsules.

### **Infections**

Oruvail may hide signs of infections such as fever and pain. It is therefore possible that Oruvail may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

### **Children**

Oruvail Capsules are not recommended for children.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Oruvail Capsules can affect the way some other medicines work. Also some medicines can affect the way Oruvail Capsules work.

### **In particular, tell your doctor if you are taking any of the following:**

- Other Non-Steroidal Anti-Inflammatory Drugs such as aspirin or ibuprofen
- Water tablets (diuretics)
- Medicines for high blood pressure or heart failure
- Cardiac glycosides such as digoxin – used for controlling heart rate or helping in heart failure
- Nicorandil – used for treating chest pain
- Medicines to stop your blood clotting such as heparin, warfarin, clopidogrel, ticlopidine, dabigatran, apixaban, rivaroxaban or edoxaban
- Medicines to dissolve blood clots such as streptokinase, alteplase, reteplase or tenecteplase
- Tenofovir used to treat HIV and hepatitis (liver disease)
- Medicines for infections (antibiotics) such as ciprofloxacin, levofloxacin, ofloxacin or trimethoprim
- Medicines for depression such as fluoxetine, sertraline, citalopram or paroxetine
- Corticosteroids – used for inflammation such as hydrocortisone, betamethasone or prednisolone
- Cyclosporin – used after an organ transplantation to help prevent rejection
- Lithium – used for some types of mental illness
- Methotrexate – used for some types of cancer or psoriasis
- Pentoxifylline – used to help poor blood circulation in limbs
- Tacrolimus – used after an organ transplant
- Probenecid – used for gout

### **Pregnancy and breast-feeding**

Do not take this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

You should not breast-feed if you are using Oruvail Capsules. This is because small amounts may pass into mothers' milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Do not take Oruvail Capsules if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Oruvail Capsules during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Oruvail Capsules can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

### **Driving and using machines**

You may feel sleepy, dizzy or faint while taking this medicine. If this happens, do not drive or use any tools or machines.

### **Important information about some of the ingredients of Oruvail Capsules**

Contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. How to take Oruvail Capsules

Always take Oruvail Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

#### Taking this medicine

- Take this medicine by mouth.
- Swallow the capsules whole with a drink of water.
- Take with or after food.
- **Do not** crush or chew your capsules.
- The dose will depend on your body weight and how severe your pain is.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
- These are slow release capsules so you will feel the effects for up to 16 hours.

#### How much to take

##### Adults

The usual dose is one capsule each day.

##### Children

Oruvail Capsules are not recommended for children.

##### The elderly

You are more likely to get side effects while taking Oruvail Capsules. Your doctor may start you on the lowest strength.

#### If you take more Oruvail Capsules than you should

If you take more capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen, feeling drowsy, stomach pains, being sick, feeling faint due to low blood pressure, difficulty breathing, wheezing, tightness in the chest or blood in your stools.

#### If you forget to take Oruvail Capsules

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, Oruvail Capsules can cause side effects, although not everybody gets them.

**Stop taking and see your doctor or go to a hospital straight away if:**

**Rare (may affect up to 1 in 1,000 people)**

- You have an asthma attack
- You have a burning, aching pain in your stomach, with an empty feeling and hunger. This may be caused by an ulcer in your stomach or gut

**Frequency not known**

- You get blistering, peeling or bleeding on any part of your skin with or without an itchy, lumpy rash. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may also have flu like symptoms at the same time. These could be symptoms of a serious skin condition such as Exfoliative Dermatitis, Stevens Johnson Syndrome or Toxic Epidermal Necrolysis, which can be fatal
- You have blood in your urine, change in the amount of urine you produce or swelling especially of your legs, ankles or feet. This may be caused by serious kidney problems
- You get chest pain or a sudden severe headache. Medicines such as Oruvail Capsules may be associated with a small increased risk of heart attack (myocardial infarction) or stroke
- You get swelling of your face, lips or throat which makes it difficult to swallow, breathe or you may have wheezing or tightness in the chest, as well as itching and rashes. These may be signs of a severe allergic reaction which could lead to anaphylactic shock, which can be fatal
- You are vomiting blood, have severe stomach pains or pass dark, tarry stools. These could be symptoms of gastrointestinal haemorrhage or perforation, which can be fatal.
- You have a fever or chills, sensitivity to light, stomach ache or headache, feel fatigued and nauseous. These could be symptoms of aseptic meningitis.

**Tell your doctor as soon as possible if you have any of the following side effects:****Rare (may affect up to 1 in 1,000 people)**

- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia).
- You bruise more easily than usual or have bleeding that lasts a long time. This could be because of a serious blood problem.
- You have pale skin and feel tired, faint or dizzy. You may have anaemia.
- You have blurred eyesight.
- Your eyes or skin go yellow (jaundice). This may be a sign of liver problems.

**Frequency not known**

- Worsening of your Crohn's disease or colitis
- Skin reaction to light or sunlamps (photosensitivity)
- Hair loss
- You may get more infections more easily than usual. This could be because of a serious blood disorder.
- Fits
- Pain in your eyes

**Other side effects:****Common (may affect up to 1 in 10 people)**

- Indigestion, heartburn, stomach pain, these are reduced by taking the medicine with food.
- Feeling nauseous or vomiting

**Uncommon (may affect up to 1 in 100 people)**

- Constipation, diarrhoea or wind
- Rash and itching
- Water retention which may cause swollen arms or legs
- Headaches, feeling dizzy, feeling drowsy or sleepy, feeling tired or unwell

**Rare (may affect up to 1 in 1,000 people)**

- Ringing in your ears (tinnitus)
- Weight gain
- Inflamed mouth

**Frequency not known**

- Balance problems (vertigo), feeling dizzy
- Feeling sleepy or being unable to sleep, changes in mood
- High blood pressure
- Changes in the way things taste
- Runny nose, itching, sneezing and stuffy nose
- Flushing
- Depression
- Feeling confused
- You see or hear things that are not there
- Heart Failure
- Vasodilation (widening of blood vessels)
- Elevated potassium levels (hyperkalaemia), symptoms include muscle cramps, diarrhoea, nausea, dizziness or headache

**Blood tests**

The results of a blood test may show changes in the way your liver or kidney is working.

These side effects may go away during treatment as your body gets used to the medicine.

**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 Website: [www.hpra.ie](http://www.hpra.ie)

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

**5. How to store Oruvail Capsules**

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

Do not take Oruvail Capsules after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

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 Oruvail Capsules contain**

- Each of the 200mg prolonged release capsules, hard, contains 200mg of the active substance, ketoprofen.

The capsules also contain the following ingredients: Capsule Contents: sugar spheres (sucrose & maize starch), colloidal anhydrous silica, shellac, ethylcellulose, talc. Capsule Shell: erythrosine E127, titanium dioxide E171, gelatin. Printing Ink: shellac glaze, indigo carmine aluminum lake, titanium dioxide E171.

Oruvail Capsules are available in blister packs of 28 capsules.

**What Oruvail Capsules look like and contents of the pack**

- Oruvail Capsules have a transparent pink body with opaque white cap with the product name 'Oruvail 200' imprinted on both sections and contain off-white to cream spherical shaped pellets. They are supplied in blister packs of 28 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

sanofi-aventis Ireland Ltd. T/A SANOFI

Citywest Business Campus

Dublin 24, Ireland.

Tel: 01 403 5600

Fax: 01 403 5687

email: IEmedinfo@sanofi.com

Manufacturer

FAMAR HEALTH CARE SERVICES MADRID, S.A.U.,

Avenida de Leganes , 62

28923 Alcorcon

Madrid, Spain.

And

Sanofi Winthrop Industrie

1, rue de la Vierge

Ambares et Lagrave

3565 Carbon Blanc Cedex

France.

This leaflet was last revised in June 2023

© SANOFI, 2020