

Package Leaflet: Information for the User
Oruvail® 200mg Prolonged-Release Capsules, Hard
(ketoprofen)

Your medicine is known by the above name, but will be referred to as Oruvail® Capsules throughout this leaflet

This medicine is also available in another strength.

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 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

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 (such as ankylosing spondylitis)
- 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 Oruvail® Capsules if:

- You are allergic to:
 - ketoprofen
 - aspirin
 - any other Non-Steroidal Anti-Inflammatory Drug (NSAID) such as ibuprofen or indometacin
 - 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.

- You have or have ever had an ulcer or bleed in your stomach or intestine (gut).
- You have severe heart problems.
- You have severe liver or kidney problems.
- You bruise more easily than usual and have bleeding that lasts a long time.
- You are in the last 3 months of your pregnancy (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

Talk to your doctor or pharmacist before taking your medicine if:

- You are asthmatic.
- You have ulcerative colitis or Crohn's disease.
- You have a disease affecting the skin, joints or kidneys called 'Systemic Lupus Erythematosus' (SLE).
- You are 65 years of age or older.
- You are planning to become pregnant or you have problems becoming pregnant. Oruvail® Capsules may make it more difficult to become pregnant.
- You have heart problems, previous stroke or think that you might be at risk of these conditions (if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- You are having or have had heart bypass surgery
- You have an infection – please see heading 'Infections' below.

Medicines such as Oruvail® 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.

Infections

Oruvail® Capsules may hide signs of infections such as fever and pain. It is therefore possible that Oruvail® Capsules 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.

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.

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

Other medicine and Oruvail® Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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
- 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
- Medicines for infections (antibiotics) such as ciprofloxacin, levofloxacin or ofloxacin
- Medicines for depression such as fluoxetine, sertraline, citalopram or paroxetine
- Corticosteroids – used for inflammation such as hydrocortisone, betamethasone or prednisolone
- Ciclosporin – used after an organ transplantation to help prevent rejection
- Mifepristone – used to terminate a pregnancy. It is important that Oruvail® Capsules are not taken for 8-12 days after taking Mifepristone.
- 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

- Tenofovir – used for HIV
- Tacrolimus – used after an organ transplant
- Probenecid – used for gout
- Zidovudine – used for HIV

Pregnancy and breast-feeding

Do not take Oruvail® Capsules if you are in the last 3 months of pregnancy as it could harm 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.

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.

Driving and using machines

You may feel sleepy, dizzy, faint, your eyesight may be affected or you may have a fit while taking this medicine. If this happens, do not drive or use any tools or machines.

Oruvail® Capsules contain sugar.

Take this into account if you have diabetes.

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.

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.
- 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. This may mean you are having a severe allergic reaction (anaphylactic reaction). These reactions can be fatal especially if you are allergic (hypersensitive) to Non-steroidal anti-inflammatory drugs such as ibuprofen.

Not known (frequency cannot be estimated from the available data)

- 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. You may have a serious skin problem which can be fatal and needs urgent medical treatment.
- 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 are vomiting blood, have severe stomach pains or pass dark, tarry stools which can be fatal.

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.

Not known (frequency cannot be estimated from the available data)

- Worsening of your Crohn's disease or colitis
- Skin reaction to light or sunlamps (photosensitivity)
- Hair loss
- Frequent infections such as fever, sever chills, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia.
- You may get more infections more easily than usual. This could be because of a serious blood disorder called leucopenia.
- Fits
- Pain in your eyes
- Nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath.
- You get breathlessness, extreme tiredness and ankle swelling. This may be signs of a heart failure.

Other possible 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 sick (nausea) or being sick (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

Very rare (may affect up to 1 in 10,000 people)

- Severe stomach or back pain. These could be signs of pancreatitis.

Not known (frequency cannot be estimated from the available data)

- 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
- Inflammation of blood vessels, which is often associated with a skin rash or bruising
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma
- Elevated potassium level (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 the Yellow Card Scheme at: 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 ORUVAIL® CAPSULES

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Protect from moisture.
- Store in a dry place.
- Keep in the outer carton to protect from light.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 Oruvail® Capsules contain

Each capsule contains 200mg of the active substance, ketoprofen. Also contains sugar spheres, colloidal anhydrous silica, shellac, ethylcellulose, talc, gelatine, erythrosine (E127) and titanium dioxide (E171).

What Oruvail® Capsules look like and contents of the pack

Oruvail® 200mg Capsules are hard gelatin capsules, with a clear pink base and a white opaque cap. The base and cap have printed 'Rofenid 200 LA' in blue and contains off-white to cream spherical pellets.

They are supplied in blisters packs of 28 capsules.

Manufactured by Famar Health Care Services Madrid, S.A.U., Avda. Leganés, nº 62, 28923 Alcorcón, Madrid, Spain

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

Revision date: 18.09.2023

PLGB 16378/0796

POM

Oruvail® is a registered trademark of Sanofi.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Beachcourse,
Tel: 020 8896 9054 for help.
Ref. number: 0796/V2**