Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user Piroxicam Dispersible Tablets, Piroxicam Injection (Intramuscular Solution) DOLONEX® DT/DOLONEX® IM

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

- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dolonex (Piroxicam) is and what it is used for
2. What you need to know before you take Dolonex (Piroxicam)
3. How to take Dolonex (Piroxicam)
4. Possible side effects
5 How to store Dolonex (Piroxicam)
6. Contents of the pack and other information

1. What Dolonex (Piroxicam) is and what it is used for

Piroxicam is a non-steroidal anti-inflammatory drug (NSAID) that also has analgesic and antipyretic properties. It is used for following indications:

Piroxicam Dispersible Tablets:

Anti-inflammatory Agent – Indicated in the treatment of pain and inflammation associated with conditions like rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis, other musculoskeletal disorders, tendinitis, bursitis, post traumatic disorders, post operative pain, primary dysmenorrhea, ankylosing spondylitis, cervical spondylitis and for the relief of fever and pain associated with acute upper respiratory tract inflammation.

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Piroxicam Intramuscular Injection:

Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma, and in primary dysmenorrhea (12 years age or older).

2. What you need to know before you take Dolonex (Piroxicam)

Do not use Dolonex (Piroxicam)

- if you are allergic to piroxicam or any of the other ingredients of this medicine (listed in section 6);
- if you have previously had or currently have a stomach and/or intestinal ulcer, bleeding or perforation in the gastrointestinal tract;
- if you have active peptic ulcers;
- if you have severe liver failure;
- if you have severe renal failure;
- if you have severe heart failure;
- in the management of perioperative pain during coronary artery bypass surgery;
- if you are pregnant.

If you belong to any of the above groups, do not take piroxicam. **Tell your doctor immediately, if any of the above applies to you.**

Warnings and precautions

Talk to your doctor or pharmacist before using Dolonex (Piroxicam).

Before prescribing Dolonex (Piroxicam), the doctor should assess the benefit/risk ratio of the side effects. Like all non-steroidal anti-inflammatory drugs, Dolonex (Piroxicam) can cause serious gastrointestinal adverse reactions, such as pain, bleeding, ulceration and perforation.

The concomitant use of Dolonex (Piroxicam) with systemic NSAIDs other than low-dose acetylsalicylic acid should be avoided due to an increased incidence of gastrointestinal ulceration and bleeding.

You should stop taking Dolonex (Piroxicam) immediately and seek medical attention if you have stomach pain or any signs of gastrointestinal bleeding, such as black or bloody stools, vomiting blood, or ulceration of the gastrointestinal tract.

If you have a rash or any other skin symptoms, as well as any allergic reaction, such as, for example, swelling of the face, wheezing or difficulty breathing, you should stop taking piroxicam immediately, seek prompt medical advice and tell your doctor that you are taking this medicine.

If you are over 70 years of age or you are concurrently taking other medicines, such as corticosteroids or certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or low-dose acetylsalicylic acid, your doctor may prescribe a medicine to protect your stomach and intestines together with Dolonex (Piroxicam).

To reduce the potential risk of cardiovascular side effects, your doctor will decide on an appropriate dose adjustment (the lowest effective dose of piroxicam for the shortest possible time is recommended). Physicians and patients should be alert to the occurrence of

cardiovascular side effects. Your doctor will inform you of the symptoms and/or signs of a toxic effect and the action to be taken if such symptoms occur.

Piroxicam may cause fluid retention and oedema, so caution should be exercised when using Dolonex (Piroxicam) in patients with impaired heart function and other conditions that may lead to fluid retention, and when the patient's condition may worsen as a result of fluid retention. If you have congestive heart failure or hypertension, you should have appropriate check-ups.

As with all NSAIDs, Dolonex (Piroxicam) may lead to hypertension or worsen pre-existing hypertension, which may contribute to an increased incidence of cardiovascular events. NSAIDs, including Dolonex (Piroxicam), should be used with caution in patients with hypertension. Blood pressure should be closely monitored when starting treatment and during treatment with Dolonex (Piroxicam).

Fluid retention and oedema have been observed in some patients taking NSAIDs, including Dolonex (Piroxicam). Therefore, caution should be exercised when using Dolonex (Piroxicam) in patients with cardiac dysfunction and other diseases that cause or exacerbate fluid retention. Patients with congestive heart failure or hypertension should be closely monitored.

Caution should be exercised when initiating treatment with piroxicam in patients with renal disease and in patients with significant dehydration. Your doctor will decide on an appropriate dose adjustment and on appropriate tests to be performed.

Dolonex (Piroxicam) may cause jaundice and hepatitis resulting in death. Although the above reactions are rare, if abnormal liver function test results persist or worsen, with the onset of symptoms indicative of hepatic impairment and/or liver disease, or with systemic symptoms (such as eosinophilia [increase in blood eosinophils], rash, etc.), stop taking Dolonex (Piroxicam).

You should have an eye exam if you have problems with your vision during treatment with piroxicam.

Medicines such as Dolonex (Piroxicam) may be associated with a small increase in the risk of a heart attack or stroke. This risk increases with long-term, high-dose treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke or think you might be at risk of suffering these conditions (for instance, you have high blood pressure, diabetes, increased cholesterol or are a smoker), ask your doctor or pharmacist about this treatment.

If you are suspected or diagnosed with reduced activity of the so-called CYP2C9 enzyme system, caution should be exercised due to the possibility of increased drug concentrations in the blood.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely with the use of Dolonex (Piroxicam), appearing initially as reddish target-like spots or circular patches often with central blisters.

Additional symptoms may occur, such as ulceration of the mouth, throat, nose and genitals, and conjunctivitis (red and swollen eyes).

These life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to wide-spread blistering or peeling of the skin.

The highest risk of serious skin reactions is within the first weeks of treatment.

If you develop Stevens-Johnson syndrome or toxic epidermal necrolysis during treatment with Dolonex (Piroxicam), you must never resume treatment with this medicine.

Concomitant use of Dolonex (Piroxicam) with oral anticoagulants (warfarin and/or coumarin derivatives and new oral anticoagulants [such as apixaban, dabigatran, rivaroxaban]) increases the risk of gastrointestinal and non-gastrointestinal bleeding.

If you develop a rash or other skin symptoms, you should seek prompt medical advice and tell your doctor that you are taking this medicine.

Other medicines and Dolonex (Piroxicam)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Medicines can sometimes interact with each other. Your doctor may limit your use of piroxicam or other medicines, or may recommend that you take a different medicine. It is especially important to tell your doctor:

- if you are taking acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs for pain relief;
- if you are taking glucocorticosteroids, which are medicines used to treat diseases such as allergies and endocrine disorders and/or hormone imbalances;
- if you are taking anticoagulants, to prevent blood clots;
- if you are taking medicines used to treat depression, called selective serotonin reuptake inhibitors (SSRIs);
- if you are taking any medications, such as acetylsalicylic acid, to prevent platelet aggregation; Dolonex (Piroxicam) interferes with the antiplatelet effect of low-dose acetylsalicylic acid and may therefore adversely affect prophylactic treatment of cardiovascular disease with acetylsalicylic acid;
- if you are taking antihypertensives, including diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II AT1 receptor antagonists (AIIA) and ß-blockers;
- if you are taking cardiac glycosides (digoxin and digitoxin);
- if you are taking cimetidine (a medicine mainly used in the treatment of gastric and duodenal ulcers);
- if you are taking cholestyramine (a cholesterol-lowering medicine);
- if you are taking cyclosporine (an immunosuppressive medicine used for example in transplant patients);
- if you are taking lithium and other medicines that bind to plasma proteins;
- if you are taking methotrexate (a medicine used to treat for example cancer and rheumatoid arthritis);

- if you are taking tacrolimus (an immunosuppressive medicine used to treat for example atopic dermatitis).

Pregnancy, breast-feeding and fertility

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.

Pregnancy:

Dolonex (Piroxicam) should not be used during pregnancy.

Breast-feeding:

Piroxicam is excreted in human milk, therefore the use of Dolonex (Piroxicam) in breastfeeding women is not recommended.

Fertility:

Due to their mechanism of action, NSAIDs, including piroxicam, may delay or prevent the rupture of ovarian follicles, which is associated with reversible infertility in some women. Discontinuation of NSAIDs, including piroxicam, should be considered in women who have problems getting pregnant or are undergoing fertility tests.

Driving and using machines

The effect of piroxicam on the ability to drive and use machines has not been studied.

3. How to take Dolonex (Piroxicam)

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will give you regular check-ups to make sure you are taking the optimal dose of piroxicam. Your doctor will adjust your treatment to the lowest effective dose. Under no circumstances should you change your dose without first speaking to your doctor.

4. Possible side effects

Piroxicam is generally well tolerated. Gastrointestinal symptoms are the most commonly encountered side effects but in most instances do not interfere with the course of therapy.

The following table lists adverse drug reactions (ADRs) within each standard System Organ Class (SOC) by decreasing order of medical seriousness or clinical importance.

System Organ Class	**Adverse Drug Reactions**
Blood and lymphatic system disorders	Aplastic anaemia*, haemolytic anaemia*, anaemia*, eosinophilia*, leucopenia*, thrombocytopenia*
Immune system disorders	Anaphylaxis*, serum sickness*
Metabolism and nutrition disorders	Hyperglycaemia*, hypoglycaemia*, anorexia, fluid retention*
Psychiatric disorders	Depression*, hallucinations*, mental confusion*, mood alterations*, insomnia*, nervousness*, dream abnormalities*

Nervous system disorders	Aseptic meningitis*, paraesthesia*, headache, dizziness, somnolence, vertigo
Eye disorders	Blurred vision, eye irritation*, swollen eyes*
Ear and labyrinth disorders	Hearing impairment*, tinnitus
Cardiac disorders	Palpitations
Vascular disorders	Vasculitis*, hypertension*
Respiratory, thoracic and mediastinal disorders	Bronchospasm*, dyspnoea*, epistaxis*
Gastrointestinal disorders	Perforation*, ulceration*, pancreatitis*, gastrointestinal bleeding (including hematemesis and melena)*, gastritis*, epigastric distress, nausea, constipation, abdominal discomfort, flatulence, abdominal pain, diarrhoea, vomiting, indigestion, stomatitis, ano-rectal reactions to suppositories presenting as local pain, burning, pruritus and tenesmus and rare instances of rectal bleeding*
Hepatobiliary disorders	Fatal hepatitis*, jaundice*
Skin and subcutaneous tissue disorders	Angioedema*, Stevens-Johnson syndrome*, toxic epidermal necrolysis (Lyell's disease)*, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)*, vesiculo bullous reactions*, dermatitis exfoliative*, erythema multiforme*, photoallergic reactions*, fixed drug eruption*, non-thrombocytopenic purpura (Henoch-Schoenlein)*, onycholysis*, alopecia*, skin rash, urticaria*, pruritus
Renal and urinary disorders	Renal failure*, nephrotic syndrome*, glomerulonephritis*, interstitial nephritis*
Reproductive system and breast disorders	Female fertility decreased*
General disorders and administration site conditions	Local adverse reactions (burning sensations) or tissue damage (sterile abscess formation, fatty tissue necrosis) at the site of injection*, malaise*, edema (mainly of the ankle), transient pain upon injection*
Investigations	Reversible elevations of BUN, reversible elevations of creatinine, decreases in hemoglobin and hematocrit unassociated with obvious gastro-intestinal bleeding*, increased serum transaminase level, positive ANA*, weight increase, weight decrease*

* Adverse Drug Reaction (ADR) identified post-marketing.
Abbreviations: BUN = blood urea nitrogen; ANA = antinuclear antibody.

5. How to store Dolonex (Piroxicam)

Dispersible Tablets: Store in a dry place at a temperature not exceeding 40°C.

Injection (Intramuscular Solution): Store protected from warm temperature and light.

6. Contents of the pack and other information

What Dolonex (Piroxicam) contains:

Dispersible Tablets:

Each uncoated dispersible tablet contains Piroxicam I.P. 20 mg.

Injection (*Intramuscular Solution):*

Each ml contains Piroxicam I.P. 20 mg
Benzyl Alcohol IP (as preservative) 20 mg
Ethanol Content ……12.6 % v/v

All strengths/presentations mentioned in this document might not be available in the market.

List of excipients:

Dispersible Tablets: Dibasic calcium phosphate I.P., Lactose I.P. (Tablettose)., Microcrystalline cellulose I.P. (Avicel 102, Vivapur 102), Hydroxy propyl cellulose NF (LH 11, Low substituted), and sodium stearyl fumarate NF.

Injection (Intramuscular Solution): Sodium dihydrogen phosphate dihydrate I.P., Niacinamide I.P., Propylene glycol I.P., Ethanol (95%) I.P., Benzyl alcohol I.P., sodium hydroxide I.P., hydrochloric acid I.P., and water for injection I.P.

What Dolonex (Piroxicam) looks like and contents of the pack

Piroxicam Dispersible Tablets:
White to off-white, oblong tablet with a break line and "DOL 20"engraved on the same side and plain on the other side.

Piroxicam Injection (Intramuscular Solution):
Clear greenish- yellow colored solution.

Contents of the pack

Dispersible Tablets (20 mg): 15 tablets per blister strip, 3 strips per combistrip, 10 combistrips per carton.

Injection (Intramuscular Solution) (20 mg/ml): 1 ml and 2 ml in amber coloured ampoules.
5 ampoules in a blister strip. 20 blister in a carton.

Details of Manufacturer:

Piroxicam Dispersible Tablets 20 mg:

Pfizer Limited
Plot No. L-137, Phase III-A, Verna Industrial Estate,
Verna, Goa- 403 722

Piroxicam Injection (Intramuscular Solution) 20 mg/ml:

Sovereign Pharma Pvt. Limited,
Survey No.46/1-4, Kadaiya Village, Nani Daman- 396 210

For Pfizer limited, Mumbai-400051, India

Marketed by:

CIPLA LTD
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai· 400 013, India

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