

The PL includes alternative texts for different legal status in different countries as follows:

- [Boxed texts] are only applicable for OTC versions.

- [Grey-shaded texts in brackets] are only applicable for prescription versions.

For OTC use in Sweden, please refer to the approved Swedish package leaflet published on our Webb site.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diklotab 25 mg film-coated tablet

Diklotab 50 mg film-coated tablet

Diclofenac potassium

[Read all of this leaflet carefully before you start taking this medicine.]

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

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Diklotab carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days with migraine or 5 days with pain.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diklotab is and what it is used for
2. Before you take Diklotab
3. How to take Diklotab
4. Possible side effects
5. How to store Diklotab
6. Further information

1. WHAT DIKLOTAB IS AND WHAT IT IS USED FOR

Diklotab relieves pain and reduces inflammation. Diklotab belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory/antirheumatic medicines).

Diklotab is used to treat mild to moderate pain, such as headache, including episodic pain associated with migraine, toothache, muscle and joint pain, back pain and period pains.

Diklotab is used for short-term treatment in children and adolescents of pain related to infections with inflammation of the ear, nose or throat, acute post-operative pain after minor surgery.

2. BEFORE YOU TAKE DIKLOTAB

Do not take Diklotab

- if you are allergic (hypersensitive) to diclofenac or any of the other ingredients of Diklotab.
- if you previously have had an allergic reaction such as asthma, sneezing or a rash on taking painkillers containing acetylsalicylic acid or other drugs for pain/inflammation within the group of NSAIDs.
- if you have a severe liver disease
- if you have an increased tendency to bleeding
- if you have porphyria (metabolic disease)
- if you have or have had a stomach ulcer or duodenal ulcer
- if you have had a stomach ulcer or duodenal ulcer in relation to treatment with diclofenac or similar preparations
- if you have severe heart failure or severe kidney disease
- during the last 3 months of pregnancy.

Take special care with Diklotab

The aim should always be to take the lowest possible dose over the shortest possible treatment period in order to reduce the risk of side effects. Higher doses than the recommended dose may involve serious risks.

Seek advice from your doctor before treatment if you have or have had any of the following diseases:

- gastrointestinal or duodenal ulcer
- inflammatory bowel disease (ulcerative colitis, Crohn's disease)
- liver disease
- heart or kidney disease
- inflammation of the nasal mucous membranes, asthma, chronic obstructive lung disease, chronic infection of your airways or other allergic reactions such as hives or angiooedema (local swelling that appears periodically)
- SLE (connective tissue disease)
- blood disorders or diseases that result in an increased tendency to bleed
- high blood pressure.

During varicella (chickenpox) it is advisable to avoid the use of this drug.

Elderly persons should be aware of the greater risk of side effects that comes with increasing age.

In children and adolescents with pain related to infections with inflammation of the ear, nose or throat, the underlying disease should be treated with an antibiotic, as therapeutically appropriate. Fever alone without inflammation is not an indication.

NSAID medicines, including Diklotab, can in rare case cause gastric ulcer which may occur at any time during treatment with or without warning. If you get discomfort in your stomach or intestines, especially if you are elderly, contact your doctor.

Like other anti-inflammatory agents, Diklotab can mask the signs or symptoms of infection.

Diklotab can, in rare cases, affect the white blood cells so that your immune system is weakened. If you get an infection with symptoms such as fever and severe debilitation, or fever with local infection such as a sore throat/mouth or urinary tract problems, you should contact your doctor at once for blood tests to exclude a deficiency of white blood cells (agranulocytosis). It is important that you inform the doctor of your medication.

Discontinue Diklotab and contact your doctor at once if you get swelling of your face, tongue and/or throat and/or difficulty swallowing or hives at the same time as difficulty breathing (angioedema).

Serious skin reactions have been reported very rarely in association with the use of NSAIDs. Stop using Diklotab if you get any skin rash or damage to the mucosa and contact a doctor.

Taking Diklotab (as is the case for all drugs that inhibit cyclo-oxygenase and prostaglandin synthesis) can make it more difficult to conceive. Seek advice from your doctor if you are planning to become pregnant or if you are having problems in becoming pregnant. The effect is temporary and ceases when you stop taking these types of drugs.

Medicines such as Diklotab 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.

If you have heart problems, 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) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Diklotab may affect or be affected by other medicines containing the following active ingredients:

- medicines against blood clots (e.g. warfarin, ticlopidine, acetylsalicylic acid, heparin),
- medicines for treating diabetes, except for insulin,
- lithium or SSRIs (used for various forms of depression)
- digoxin (used for heart problems)
- tacrolimus (used during transplantations and for eczema)
- ciclosporin (used during transplantations, for severe psoriasis and for rheumatism)
- certain medicines for high blood pressure (beta-blockers, angiotensin II receptor antagonists and ACE inhibitors)
- diuretics (agents to stimulate urine production, and used against high blood pressure)
- quinolone antibiotics (used for urinary tract infection)
- corticosteroids (used to treat inflammatory diseases)
- colestipol or cholestyramine (used to treat high levels of blood fat)
- rifampicin (an antibiotic used for tuberculosis)
- carbamazepine (used for epilepsy)
- St. John's wort (used for depression)
- phenytoin (used for epilepsy)
- methotrexate (used for psoriasis, rheumatism and certain tumours)

Never take different kinds of pain-relief medicines at the same time without your doctor's prescription.

Taking Diklotab with food and drink

The tablets should be swallowed whole with liquid. To obtain the best effect, they should not be taken with or directly after a meal.

Pregnancy and breast-feeding

Diklotab must not be used during the last three months of the pregnancy. Diklotab should be avoided by women who are trying to become pregnant or who are pregnant. Treatment with Diklotab during any phase of pregnancy may only take place on the prescription of a doctor.

The medicine passes into the breast milk with the risk of affecting the child. Therefore, Diklotab shall not be used if you are breast-feeding. Ask your doctor for advice before taking any medicine while breast-feeding.

Driving and using machines

Diklotab can cause side effects such as visual problems, dizziness and sleepiness in some people.

3. HOW TO TAKE DIKLOTAB

The dose has been individually prescribed for you by a doctor. The dose and the duration of the treatment depends on the pain condition.

Always take Diklotab exactly as recommended below.
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Migraine attacks

Usual dose for adults and adolescents over 16 years: 50 mg to be taken at the first signs of a migraine attack. Another 50 mg to be taken if relief is not obtained within 2 hours. This may be repeated once more after 4–6 hours. Do not take more than 150 mg in a 24-hour period, which corresponds to 6 tablets of 25 mg or 3 tablets of 50 mg, in a 24-hours period. Do not exceed the stipulated dose.

Other acute pain conditions, such as headache, toothache, muscle and joint pain or period pains

Usual dose for adults and adolescents over 16 years: 25-50 mg to be taken every 4-6 hours as required. Do not take more than 150 mg in a 24-hour period, which corresponds to 6 tablets of 25 mg or 3 tablets of 50 mg, in a 24-hours period. Do not exceed the stipulated dose.

Children (over 9 years) and adolescents

Acute pain conditions in children and adolescents with infections with inflammation in the ear, nose and throat and after minor surgery.

Usual dose for children 9-11 years (over 35 kg): 1 tablet 25 mg 3 times daily evenly distributed during 24 hours. Do not exceed the stipulated dose.

Usual dose for children 12-16 years: 1 tablet 25 mg 3-4 times daily evenly distributed during 24 hours. Do not exceed the stipulated dose.

The tablets should be swallowed whole with liquid. To obtain the best effect, they should not be taken with a meal.

Seek advice from your doctor or pharmacist if you are unsure. Contact your doctor or pharmacist if you think that the effect Diklotab has too strong or too weak.

If you take more Diklotab than you should

If you have taken more Diklotab than you should, or if a child has been taking Diklotab by accident, please contact your doctor or hospital to get an opinion of the risk and advice on action to be taken.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diklotab can cause side effects, although not everybody gets them. You may experience gastrointestinal problems at the beginning of treatment. These side effects normally disappear within a few days.

Common (occur in more than 1 in 100 patients): Abdominal pain, nausea, vomiting, diarrhoea, digestive problems, reduced appetite, flatulence, headache, dizziness, vertigo, rash and raised liver values.

Uncommon (occur in less than 1 in 100 patients): Convulsions in the windpipe.

Rare (occur in less than 1 in 1,000 patients): Tiredness, swelling of the body as a result of fluid retention, hypersensitivity reactions (hives, allergic shock reaction with a fall in blood pressure), stomach ulcer, stomach haemorrhage (vomit mixed with blood, blood in the stools, haemorrhagic diarrhoea), problems with the large intestine (constipation, inflammation of the bowel), deterioration of Crohn's disease and ulcerative colitis, inflammation of the tongue, mouth or oesophagus, inflammation of the pancreas, impotence (the association here is uncertain), asthma (including difficulty breathing), liver function disorders (liver inflammation, jaundice).

Very rare (occur in less than 1 in 10000 patients): Effects on vision (blurred vision, double vision) and hearing (reduced hearing, tinnitus), difficulties in sleeping, nightmares, irritability, anxiety, depression, memory disturbances, confusion, a disturbed sense of reality, paraesthesia, tremors, convulsions, disturbances of sensation, changes in the sense of taste, effects on the heart and blood vessels (such as chest pains, tachycardia, high blood pressure, heart failure, heart attack, inflammation of blood vessels), effects on blood composition (a reduced number of blood platelets, which can lead to small haemorrhages in the skin and mucous membranes, a reduced number of white blood cells (agranulocytosis), which can weaken the immune response, breakdown of red blood cells, (anaemia), eczema, itching, redness of the skin, serious skin reactions including Stevens-Johnson syndrome (inflammation of the mucous membrane and skin with blisters and high fever) and Lyells syndrome (like Stevens-Johnson syndrome but with sudden sloughing of the skin in addition), hair loss, hypersensitivity to light, effects on the kidneys (e.g. reduction or stoppage in urine production and blood in the urine), inflammation of membranes of the brain or the lungs with no bacterial cause, stroke, angioedema (e.g. swelling of the face, rash, difficulty breathing).

Exceptionally, serious infections of the skin in case of varicella.

Medicines such as Diklotab may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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

5. HOW TO STORE DIKLOTAB

Keep out of the reach and sight of children.

Do not use Diklotab after the expiry date stated on the pack after Exp. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Diklotab contains

- The active substance is diclofenac potassium. Each tablet contains 25 mg or 50 mg diclofenac potassium.
- The other ingredients are potassium hydrogen carbonate, mannitol, sodium lauryl sulphate, macrogol, crospovidone, magnesium stearate, hypromellose.

What Diklotab looks like and contents of the pack

The tablets are white, round and biconvex.

Blister packs (25 mg) containing 10, 12, 18, 20, 30, 40, 80, 100 and 120 tablets.

Blister packs (50 mg) containing 20, 30, 40, 50, 60, 80, 100 and 120 tablets.

Not all package sizes may be marketed.

Marketing Authorisation Holder

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