

PACKAGE LEAFLET: INFORMATION FOR THE USER

DALSY

20 mg/ml oral suspension

IBUPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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

1. WHAT DALSY IS AND WHAT IT IS USED FOR

Dalsy oral suspension contains the active substance ibuprofen, which belongs to the group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

Dalsy can be used to relieve pain and inflammation in diseases such as rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis, gout, swollen joints, painful shoulder, bursitis, tendonitis, tenosynovitis, pain in the lower back, sprains and strains.

It can also be used for relief of mild to moderately severe pain of different origin, such as toothache, pain after surgery, menstrual pain, pain after episiotomy, postnatal pain and headaches, including migraines.

Dalsy is also used for short-term treatment of fever in children over three months (body weight over 5 kg).

2. BEFORE YOU TAKE DALSY

Do not take Dalsy:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)

- If you are suffering from hypersensitivity reactions (bronchospasm, asthma, rhinitis, angioedema or urticaria) to acetylsalicylic acid or other anti-inflammatory drugs
- If you have a history of bleeding or rupture in the gastrointestinal tract associated with the use of medicines from the group of NSAIDs
- If you have a stomach ulcer / duodenal ulcer or bleeding in the digestive system or have had a recurring ulcer / duodenal ulcer or gastrointestinal hemorrhage (two or more distinct episodes of ulcers or bleeding)
- if you have severe liver and kidney disease
- if you have severe heart failure
- If you have an increased tendency to bleed or an active bleeding (including bleeding in the brain)
- If you are in the last trimester of pregnancy
- if you have severe dehydration (pronounced loss of body water caused by vomiting, diarrhea or insufficient fluid intake)

Warnings and Precautions

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before taking Dalsy oral suspension:

- you have had or still have chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease)
- You had a disease of the digestive system, since it is possible worsening of the disease. If during administration of Dalsy oral suspension, especially at the beginning of treatment, you experience any unusual symptom in the abdomen consult a doctor. In case of bleeding or ulcers in the digestive system, immediately stop taking the medicine and consult a doctor.
- have or have had asthma or allergic disease because there is increased risk of narrowing of the airways with difficulty in breathing (bronchospasm)
- You suffer from seasonal allergic rhinitis, nasal polyps or chronic obstructive respiratory disorders, because there is increased risk of allergic reactions. They can manifest itself as asthma attacks, Quincke's edema or urticaria.
- you have problems with your liver, kidney, heart or high blood pressure
- You are prone to bleeding and / or taking medicines that affect blood clotting.
- you are pregnant or breast-feeding
- you have chickenpox
- you suffer from systemic lupus erythematosus and mixed connective tissue disease (a disease that affects the skin, joints and kidneys)
- you have dehydration (water loss from the body caused by vomiting, diarrhea or insufficient fluid intake)
- you are elderly, because potential for side effects is higher (especially bleeding, ulcers and ruptures in the gastrointestinal tract)
- You have inherited intolerance to some sugars.

Like other anti-inflammatory drugs, Dalsy can mask signs of infection.

During the prolonged use of analgesics may experience headaches that cannot be treated with increased doses of medicine.

Heart attack and stroke

Anti-inflammatory drugs / painkillers such as ibuprofen may be associated with a slightly increased risk of heart attack or stroke, particularly when used in high doses.

Do not exceed the recommended dose or duration of treatment.

Contact your doctor or pharmacist before taking Dalsy oral suspension:

- If you have heart problems, including heart failure, angina (chest pain), or if you have had a heart attack, bypass, peripheral arterial disease (poor circulation in the feet due to narrow or blocked arteries), or any kind of stroke (including "mini stroke" or transient ischemic attack).

- if you have high blood pressure, diabetes, high cholesterol, history of heart disease or stroke in the family, or if you are a smoker.

If any of the above applies to you, talk to your doctor or pharmacist before taking Dalsy oral suspension.

The lowest effective dose

You should always take the smallest effective dose to reduce the risk of side effects. Taking a higher dose than recommended could increase the risk of side effects.

Children

There is a risk of kidney damage in dehydrated children and adolescents.

Ibuprofen is not recommended for children weighting less than 5 kg.

Other medicines and Dalsy oral suspension

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

Dalsy can affect or be affected by treatment with certain medicines, including:

- other anti-inflammatory drugs to relieve pain, including selective inhibitors of cyclooxygenase-2 (COX-2)
- cardiac glycosides (digoxin)
- corticosteroids (for treating inflammation)
- medicines that are anti-coagulants (eg. Dilute the blood / prevent blood clotting, such as aspirin / aspirin, warfarin)
- antithrombotics (clopidogrel and tiklodipin)
- selective serotonin reuptake inhibitors (for treating depression)
- lithium
- aspirin
- medicines that reduce high blood pressure (such as the ACE inhibitors captopril, beta blockers such as atenolol, antagonists of the angiotensin-II as losartan)
- Duretic (medicines for urination)
- zidovudine (antiviral drug)
- methotrexate (used to treat some cancers)
- cyclosporin or tacrolimus (immunosuppressive medicines used after organ transplants, or to treat autoimmune diseases)
- some antibiotics to treat the infection (quinolones, aminoglycosides)
- mifepristone
- the group of sulfonylurea medicines (for treating diabetes)
- cholestyramine (used to treat high cholesterol levels)
- herbal preparations containing ginkgo biloba
- voriconazole or fluconazole (medicines to treat fungal infections)
- alcohol
- phenytoin (for epilepsy)
- probenecid and sulfinpyrazone

If any of these apply to you or you are not sure, talk to your doctor or pharmacist before taking Dalsy oral suspension.

Treatment with Dalsy oral suspension could also affect other medicines or they might affect Dalsy oral suspension. Always check with your doctor or pharmacist before using Dalsy oral suspension with other medicines.

Dalsy oral suspension with food, drink and alcohol

Dalsy oral suspension can be taken simultaneously with food and drink.

During concomitant administration of alcohol you may experience an increase of the side effects of NSAID medicines, particularly those involving gastrointestinal or central nervous system. Also, ibuprofen in combination with alcohol can affect your response time i.e. vigilance.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During the first six months of pregnancy ibuprofen should not be used except in necessary cases according to the advice of a doctor. Ibuprofen should not be used in the last trimester of pregnancy.

It should not be administered during breastfeeding.

The use of ibuprofen may reduce female fertility and is not recommended for women who are trying to conceive.

Driving and using machines

Ibuprofen may affect your reaction time. It may cause dizziness, drowsiness, fatigue and vision problems. Caution should be exercised when driving a vehicle, operating machinery or performing tasks that require alertness. This applies to a greater extent when ibuprofen is used in combination with alcohol.

Important information about some of the ingredients of Dalsy

Dalsy oral suspension contains Methylparahydroxybenzoate (E218) and Propylparahydroxybenzoate (E216).

They can cause allergic reactions (possibly delayed hypersensitivity reactions).

Dalsy oral suspension contains sucrose and sorbitol.

If you are told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine. This should be taken into account in patients with diabetes mellitus. It can damage the teeth.

Dalsy oral suspension contains a yellow azo dye Sunset Yellow (E110).

It may cause allergic reactions.

3. HOW TO TAKE DALSY

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

Dosage

Adults and adolescents (over 12 years; body weight above 40 kg): The recommended dose is 1200• 1800 mg per day in divided doses. In some cases, a lower dose of 600-1200 mg can be administered. In severe and acute conditions, the dose can be increased up to the point of establishing control of the acute condition in which the total daily dose should not exceed 2400 mg.

The space between the individual doses should not be less than 4 hours.

Children older than 3 months (body weight of 5 kg): The usual daily dose is 20-30 mg per kg of body weight taken at intervals. This can be achieved in the following way:

Weight	Age	Dose
5-7 kg	3-6 months	2.5 ml 3 times daily
7-10 kg	6-12 months	2.5 ml 3 times daily
10-14.5 kg	1-2 years	2.5 ml 3-4 times daily
14.5-25 kg	3-7 years	5 ml 3-4 times daily
25-40 kg 8-12 years	10 ml 3-4	times daily

Dalsy oral suspension should not be given to children with a body weight less than 5 kg.

In cases of juvenile rheumatoid arthritis, the doctor may increase the dose up to 40 mg / kg body weight taken at intervals.

Elderly: No special dose adjustment unless you have impaired kidney or liver function when you may require that your doctor adjusts the dose individually.

Kidney and liver impairment: reduction of dose is not necessary if you have mild to moderate kidney or liver impairment. In the case of severe kidney or liver impairment, you must not take this medicine.

Method of administration

For oral use.

Packaging contains 5 ml dosing syringe / a 2.5 ml/5 ml double dosing spoon.

The vial should be shaken well before use.

To achieve a rapid onset of action, the dose may be taken on an empty stomach. If you have a sensitive stomach it is recommended to take Dalsy oral suspension with food.

You may also experience a burning sensation in the mouth or throat.

If you take more Dalsy than you should

If you or someone else inadvertently have taken significantly higher dose than recommended (overdose), immediately tell your doctor or contact nearest hospital emergency department.

If there was an overdose with significant quantities of Dalsy oral suspension, symptoms usually occur within 4-6 hours, and the most common are nausea, vomiting, abdominal pain, numbness and dizziness.

If you forget to use Dalsy

If you forget to take a dose, do it as soon as possible unless it is almost time for your next dose. In that case, do not take the missed dose. Do not use a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

If the following side effects occur, stop taking the medicine and contact your doctor:

- Skin rash, mucosal injury, or other signs of skin sensitization
- Swelling of the face, tongue, throat, difficulty in breathing (angioedema, anaphylactic shock)
- Occurrence or worsening signs of infection (eg, soft tissue necrosis), especially with chickenpox
- Severe headache, fever, stiff neck, sensitivity to light
- Bloody diarrhea
- Extremely dark colored stools (as tar)
- Vomiting fresh blood or dark pieces that look like coffee beans.

The following side effects may occur with use of this product:

Common (can occur between 1 and 10 in 100 patients)

- Dizziness, headache
- Indigestion, diarrhea, nausea, vomiting, abdominal pain, bloating, constipation, blood in the stool, vomiting blood, bleeding in the digestive system
- rash
- tiredness.

Uncommon (can occur between 1 and 10 in 1,000 patients)

- Runny nose (rhinitis)

- hypersensitivity
- Insomnia, anxiety
- Unusual sensations on the skin such as numbness, tingling, pricking, burning or tingling (paraesthesia), sleepiness
- Visual disturbances
- Disorders of hearing, tinnitus, dizziness (vertigo)
- Asthma, bronchial tightness (bronzospazam), dyspnoea
- Gastritis, duodenal ulcer / stomach ulcer (ulcers) in the mouth, a rupture in the digestive system
- Inflammation of the liver (hepatitis), jaundice, hepatic dysfunction
- Hives, itching, purpura, angioedema, photosensitivity
- Various forms of toxicity to the kidneys, including tubulointerstitial nephritis, nephrotic syndrome and renal failure.

Rare (may occur in less than 1 in 1,000 patients)

- Aseptic meningitis
- Disorders of the blood and lymphatic system (leukopenia, thrombocytopenia, aplastic anemia, neutropenia, agranulocytosis and hemolytic anemia)
- Anaphylactic reaction
- Depression, confusion, hallucinations
- Optic neuritis
- Toxic optic neuropathy
- Liver injury
- Swelling (edema).

Very rare (may occur in less than 1 in 10,000 patients)

- Heart failure, myocardial infarction
- High blood pressure
- Inflammation of the pancreas
- Liver failure
- Severe skin reactions (eg, erythema multiforme, bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis)
- Severe hypersensitivity reactions. Symptoms may include swelling of the face, tongue and throat, dyspnea, tachycardia, hypotension up to the life-threatening shock.

Unknown (frequency cannot be estimated from the available data):

- Colitis and Crohn's disease.

Reporting of side effects

If you notice any side effects, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can report side effects directly through a national system for reporting side effects: listed in Appendix V. By reporting side effects, you can contribute to the assessment of the safety of this medicine.

5. HOW TO STORE DALSY

Keep out of reach and sight of children.

Do not use Dalsy after the expiry date stated on the package. 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 Dalsy contains

1 ml of syrup contains 20 mg of ibuprofen
5 ml of syrup contains 100 mg of ibuprofen.

The other ingredients are preservatives (methyl parahydroxybenzoate E218, propyl parahydroxybenzoate E216, sodium benzoate E211), sucrose, citric acid monohydrate, glycerol, sorbitol E420, kaolin, polysorbate 80, flavouring (orange), colorant (sunset yellow E110), agar, purified water.

What Dalsy looks like and contents of the pack

Dalsy oral suspension is orange in color.
100 ml and 200 ml (plastic bottle). A 5 ml dosing syringe / a 2.5 ml/5 ml double dosing spoon is included.
Not all pack sizes may be marketed.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer:

AbbVie Srl
S.R. 148 Pontina km 52 snc
04011 Campoverde di Aprilia (LT)
Italy