Package leaflet: Information for the user

Dexibuprofen 300 mg Film-coated Tablets

Dexibuprofen

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 Dexibuprofen Tablets ares and what it is used for

The name of your medicine is Dexibuprofen 300 mg Film-coated Tablets (called as Dexibuprofen Tablets in this leaflet). Dexibuprofen tablets contain active ingredient as "dexibuprofen", which belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They work by reducing the amount of prostaglandins (substances that control inflammation and pain) your body produces.

Dexibuprofen Tablets are used to relieve:
- pain and inflammation caused by osteoarthritis/ arthritis (joint inflammation, joint wear and tear);
- period (menstrual) pain;
- mild to moderate pain, such as musculoskeletal pain, headache and toothache; painful swelling and inflammation after injury;.
- For the short-term symptomatic treatment of chronic rheumatoid arthritis (painful, degenerative joint diseases) when other long-term treatment options cannot be considered.

2. What you need to know before you take Dexibuprofen Tablets

Do not take Dexibuprofen Tablets
- if you are allergic to dexibuprofen or any of the other ingredients of this medicine (listed in section 6);
- you are allergic to acetylsalicylic acid or other painkillers. Your allergy may cause you to have difficulty breathing, asthma, a runny nose, a skin rash or swelling to your face;
- if you previously had bleedings or perforations in your gastrointestinal system caused by NSAIDs;
- you have or previously have had recurrent a stomach or duodenal ulcers (Vomiting blood or having black bowel motions or bloody diarrhoea could be a sign that your stomach or your intestines are bleeding.);
- you have bleedings in the brain (cerebrovascular bleedings) or other active bleedings;
- you currently have a flare up of an inflammatory disease of the intestines (ulcerative colitis, Crohn's disease);
- you have serious heart failure or serious liver or kidney disease;
- from the beginning of the 6th month of pregnancy.
- If you are taking dexibuprofen for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Warnings and Precautions

Other medical problems may affect how you should use dexibuprofen tablets. Before you take this medicine, make sure your doctor knows if:
- you have ever had a stomach or duodenal ulcer;
- you have had bowel ulcers, ulcerative colitis or Crohn's disease;
- you have liver or kidney disease or you are addicted to alcohol;
- you have blood clotting disorders (also see the 'Taking other medicines and Dexibuprofen Tablets' section);
- you have oedema (when fluid collects in your body tissues);
- you have a heart disease or high blood pressure;
- you have asthma, hay fever or any other breathing problems;
- you suffer from systemic lupus erythematosus (a disease which affects joints, muscles and skin) or mixed collagenosis (a collagen disease which affects connective tissues);
- you are having problems becoming pregnant. (NSAIDs such as dexibuprofen can rarely affect fertility in women. Your fertility will return to normal when you stop taking Dexibuprofen Tablets.)
- you have an infection - please see heading "Infections" below.

The risk of side effects may be increased in elderly patients.
If you need higher doses, especially if you are over 60 or if you had stomach or duodenal ulcers, there is an increased risk of gastrointestinal side effects.

This risk may be increased with other medicines you are taking. If you vomit blood, have black stools or bloody diarrhea, this could be a sign of bleeding in the stomach or intestines. Stop taking dexibuprofen tablets and see a doctor immediately.

Your doctor may consider to prescribe protective agents together with dexibuprofen tablets.

Anti-inflammatories/painkillers such as dexibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used in high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking dexibuprofen tablets if you:
- have heart disease, including heart failure (heart failure) and angina (chest pain), or have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries) or any type of stroke (including mini - had a stroke or transient ischemic attack ("TIA").
- have high blood pressure, diabetes or high cholesterol, or a family history of heart disease or stroke, or if you are a smoker.

Skin reactions

Serious skin reactions have been reported in association with treatment with dexibuprofen tablets. If you develop a skin rash, mucous membrane lesions, blisters or any other sign of allergy, you should stop taking dexibuprofen tablets and seek medical attention immediately, as these can be the first signs of a very serious skin reaction. See section 4.

Infections

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

You should avoid taking NSAIDs if you have chickenpox.
Your doctor may need to give you regular check-ups if:
- you have heart, liver or kidney problems;
- you are older than 60;
- you need to take this medicine for long-term treatment.

Your doctor will tell you how often you need these check-ups.

You can get a headache if you take high doses of painkillers for a long time (off label use). In this case you must not take more drug for the headache.

Other medicines and Dexibuprofen Tablets

Taking other medicines can sometimes affect the way that other medicines work. Please tell your doctor or pharmacist if you are taking/using or have recently taken/used or might take/ use any other medicines.

Dexibuprofen tablets may affect or be affected by other medicines. For example:
- Medicines that have an anticoagulant effect (i.e. thin the blood/ prevent clotting, e.g. acetylsalicylic acid, warfarin, ticlopidine).
- Medicines that lower high blood pressure (ACE inhibitors such as captopril, beta-blockers such as medicines containing atenolol, angiotensin II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by treatment with dexibuprofen tablets. You should therefore always seek the advice of your doctor or pharmacist before using dexibuprofen tablets with other medicines:

You **should not take** the following medicines with Dexibuprofen Tablets unless you are under close medical supervision:
- Non-steroidal anti-inflammatory drugs. There is an increased risk of ulcers and bleedings in the digestive system if you take Dexibuprofen with other NSAIDs or acetylsalicylic acid.
- Lithium used to treat certain mood disorders. Dexibuprofen can increase the effect of lithium.
- Methotrexate. Dexibuprofen can increase the side effects of methotrexate.

You **may take** the following medicines but for safety reasons you should tell your doctor:
- Certain heart medicines called ACE-inhibitors or Angiotensin II receptor antagonists. They may increase the risk of kidney problems in rare cases.
- Diuretics (water tablets).
- Corticosteroids. The risk for ulcers and bleeding may increase.
- Certain antidepressants (selective serotonin reuptake inhibitors) may increase the risk for gastrointestinal bleeding.
- Digoxin (a heart medicine). Dexibuprofen can increase the side effects of digoxin.
- Immune suppressants like ciclosporin.
- Medicines that increase potassium levels in the blood. ACE inhibitors, angiotensin-II receptor antagonists, ciclosporin, tacrolimus, trimethoprim and heparins.
- Phenytoin used to treat epilepsy. Dexibuprofen may increase the side effects of phenytoin.
- Phenytoin, phenobarbital and rifampicin. Concomitant administration may lower the effects of dexibuprofen.
- Oral antidiabetics (sulfonylureas, agents that lower blood sugar levels). Fluctuations in blood sugar can occur.
- zidovudine (used to treat HIV infection). Bleeding disorders may increase the risk of joint effusions and bruising.
- Pemetrexed (a cytotoxic drug). If you have kidney disease, high doses of dexibuprofen tablets should not be taken 2 days before or 2 days after pemetrexed administration.

Dexibuprofen Tablets with food, drink and alcohol

You may take Dexibuprofen Tablets with or without food, but it is better to take it with a meal as this may help to avoid stomach problems, particularly if you take it for long term use.

Excessive alcohol consumption can worsen the gastrointestinal tolerance of dexibuprofen tablets.

Pregnancy, lactation 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.

Do not take dexibuprofen tablets 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 dexibuprofen tablets 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, dexibuprofen tablets 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.

Only small amounts of active ingredient pass into breast milk. However, if you are breastfeeding, you should not take Dexibuprofen for long periods or in high doses.

Driving and using machines

Caution: This medicine can affect your ability to react and drive.

If you have side effects like feeling dizzy, drowsy, tired, or if you have a blurred vision after taking Dexibuprofen, you should avoid driving or using any dangerous machines (see section 4 Possible side effects).

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'.

3. How to take Dexibuprofen Tablets

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

You should take Dexibuprofen Tablets with a glass of water or some other liquid. Dexibuprofen works faster if you take it without food. Taking it with food is recommended as this may help to avoid stomach problems, particularly if you take it for long term use.

The maximum **single dose** is 1 Dexibuprofen 300 mg tablets.

The maximum **daily dose** is **4** Dexibuprofen 300 mg tablets.

Your doctor can also prescribe Dexibuprofen 200 mg or Dexibuprofen 400 mg tablets for individual dosing.

Osteoarthritis/arthrosis, chronic articular rheumatism

The usual dose is 1 Dexibuprofen 300 mg tablet 2 to 3 times a day. In acute cases, the doctor can prescribe up to 4 Dexibuprofen 300 mg tablets a day.

Painful periods (menstrual pain)

The usual dose is 1 Dexibuprofen 300 mg tablet 2 to 3 times a day.

Mild to moderate pain

The usual dose is 1 Dexibuprofen 300 mg tablet twice a day. If a higher doses is required your doctor may prescribe up to 4 Dexibuprofen 300 mg tablets a day.

The lowest effective dose should be used for the shortest time necessary to relieve symptoms. If you have an infection, consult a doctor immediately if symptoms (e.g. fever and pain) persist or worsen (see section 2).

Elderly patients (65 years and older)

If you are over 65 years old, your doctor may have prescribed a lower dose than normal. If you are not having problems taking dexibuprofen tablets, your doctor may increase your dose.

Patients with liver or kidney disease: Your doctor may have prescribed a lower than the normal dose of Dexibuprofen. You must not increase the dose your doctor has prescribed.

Use in children and adolescents

Always give your child dexibuprofen tablets exactly as your doctor has told you.

This dosage strength is not suitable for children and adolescents. Your doctor may prescribe the 200 mg divisible tablet for children over 8 years of age.

If you feel that the effects of your Dexibuprofen tablets are too strong or too weak, talk to your doctor or pharmacist.

If you take more Dexibuprofen Tablets than you should

If you have taken more tablets than you should, or if children have accidentally taken the medicine, always contact your doctor or nearest hospital for an assessment of the risk and advice on further treatment.

Symptoms of overdose may include nausea, stomach pain, vomiting (possibly with blood), headache, ringing in the ears, confusion, incoordination, and tremors in the eyes. At high doses, drowsiness, drowsiness, chest pain, palpitations, fainting, convulsions (especially in children), weakness and dizziness, blood in the urine, drop in blood pressure, feeling cold and breathing problems have been reported.

For the doctor: You will find information on symptoms and therapy in the event of overdose at the end of this leaflet

If you forget to take Dexibuprofen Tablets

Do not take a double dose to make up for a tablet you have forgotten to take. Take the next tablet as usual.

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

4. Possible side effects

Like all medicines, Dexibuprofen can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

• Liver, kidney problems or difficulty urinating

Dexibuprofen, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

These do not happen as often when you take a low dose, or you take Dexibuprofen for only a short time.

Stop taking Dexibuprofen and see a doctor:
- if you have a severe stomachache, especially when you start taking Dexibuprofen.
- if you have black stool, bloody diarrhea or if you are vomiting blood.
- if you have a skin rash, severe blistering or peeling of the skin, mucosal lesions or any signs of hypersensitivity.
- if you have symptoms like fever, sore throat and mouth, flu like symptoms, feeling tired, nose and skin bleed. These can be caused by a reduction of white blood cells in your body (agranulocytosis).
- if you have severe or persistent headache.
- if you have a yellow coloration of the skin and the whites of the eyes (jaundice).
- if you have a swollen face, tongue or pharynx, difficulty to swallow or to breath (angiooedema).

Very common side effects - affects more than 1 in 10 people
- Indigestion, stomach ache.

Common side effects - affects less than 1 in 10 but more than 1 in 100 people
- Diarrhea, vomiting or nausea;
- feeling exhausted or drowsy, dizziness, headaches;
- a skin rash.

Uncommon side effects - affects less than 1 in 100 but more than 1 in 1000 people
- Ulcers and bleeding in the stomach or intestines, black bowel motions, ulcers in the mouth, gastritis;
- purpura (purple bruises), itching, a raised itchy rash;
- swelling of the face or throat (angioedema);
- problems with sleeping, restlessness, anxiety, blurred vision, buzzing or ringing in the ears (tinnitus);
- runny nose, difficulties breathing.

Rare side effects - affects less than 1 in 1000 but more than 1 in 10,000 people
- A strong allergic reaction;
- psychotic reactions, depression, feeling irritable;
- feeling confused, disoriented or agitated;
- temporary poor eyesight;
- hearing problems;
- wind, constipation, perforations in the digestive system (symptoms are severe stomach ache, fever, feeling sick), an inflamed oesophagus, flare up of diverticular disease (small pouches in your bowels that may become infected or inflamed), colitis or Crohn's disease;
- problems with your liver, hepatitis (inflamed liver) and jaundice (yellowing of the skin or eyes);
- blood disorders, including disorders that reduce the number of white or red blood cells or platelets.

Very rare side effects - affects less than 1 user in 10,000
- Hypersensitivity reactions, including symptoms like fever, a rash, pain in the abdomen, headaches, feeling sick and vomiting;
- photosensitivity;
- aseptic meningitis (symptoms are headache, fever, stiff neck, and generally feeling ill), serious allergic reactions (difficulty breathing, asthma, a fast heartbeat, low blood pressure and shock) allergic reaction with inflamed small blood vessels;
- reddened skin, mucous membranes or throat;
- blistering hands and feet (Stevens-Johnson syndrome);
- peeling skin (epidermal necrolysis);
- hair loss;
- inflamed kidney, kidney disease or kidney failure;
- systemic lupus erythematosus (auto immune disease);
- very rare bacterial infections, which attack the tissue covering the muscle can be aggravated.

Not known: frequency cannot be estimated from the available data
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include a rash, fever, swollen lymph nodes, and an increase in eosinophils (a type of white blood cell).
- At the start of treatment, a red, scaly, widespread rash with bumps under the skin and blisters accompanied by fever, primarily on the skin folds, trunk and upper extremities (acute generalized pustular rash). Stop using dexibuprofen tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

Oedema (swollen limbs), high blood pressure and heart failure may occur with NSAID treatment.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Dexibuprofen tablets?

Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions.

Do not use this medicine 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 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 "Dexibuprofen" contains
- The active substance is dexibuprofen.
- The other ingredients are: Colloidal anhydrous silica, microcrystalline cellulose, hypromellose, croscarmellose sodium. Opadry: polyvinyl alcohol, titanium dioxide, macrogol & talc.

What "Dexibuprofen" looks like and contents of the pack

Dexibuprofen Film-coated Tablets, 300 mg
White, circular shaped, biconvex, film coated tablet with 300 debossed on one side and plain on other side. The dimension of 300mg tablet is 11.0mm ± 0.2mm.

The packs are available in blister pack of ALU-PVC/PVDC.
Package sizes: 10, 20, 30, 50, 60, 90, 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Strides Pharma UK Ltd
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS
United Kingdom

This leaflet was last revised in 06/2023.

1048492

114 x 700 mm — Front Side

114 x 700 mm — Back Side

Pharma code Position shall be changed depending upon the folding dimension as per machine requirements.

ARTWORK DETAIL LABEL

Product	**Dexibuprofen 300 mg Tablets**				
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert		
Dimension	**114 x 700 mm**			Pack	--
New Item Code	**1048492**	Old Item Code	1046536		
Colour Shades	Pantone 704 U			No. of Colours	1

Change Control No.	PC-TSG/2022/417 - Record Number: 370223	Artwork Version	4.0
Design/Style	Front & Back Printing. To be supplied in the folded size of 114 x 37.5 mm		
Substrate	60 GSM Paper.		
Special Instructions	Printing clarity to be clear & sharp.		
Autocartonator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

RD/PD/003/F-08/R0