Package leaflet: Information for the user

<X> 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 <X> is and what it is used for

Dexibuprofen, the active ingredient in <X>, belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs such as dexibuprofen are used as a painkiller and to control inflammation. They work by reducing the amount of prostaglandins (substances that control inflammation and pain) your body produces.

What is <X> used for
<X> is indicated in adults to relieve:
- pain and inflammation caused by osteoarthritis (when your joints become worn);
- period (menstrual) pain;
- mild to moderate pain, such as pains in the muscles and joints, and toothaches.

2. What you need to know before you take <X>

Do not take <X> 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);
- you previously had bleedings or perforations in your gastrointestinal system caused by NSAIDs;
- you have or previously have had recurrent stomach or duodenal ulcers (vomiting blood or having black bowel motions or bloody diarrhoea could be a sign that your stomach or your intestine 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 intestine (ulcerative colitis, Crohn's disease);
- you suffer from severe dehydration (e.g. caused by vomiting, diarrhoea or insufficient fluid intake);
- you have serious heart failure or serious liver or kidney disease;
- you are a woman in the third trimester of pregnancy;
- you suffer from a condition of unknown origin resulting in abnormal formation of blood cells.

Warnings and precautions
Talk to your doctor or pharmacist before taking <X>, 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 'Other medicines and <X> section);
- you have oedema (when fluid collects in your body tissues);
- you have a heart disease or high blood pressure;
- 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;
- you suffer or have suffered from asthma or allergic diseases, as shortness of breath may occur;
- you suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders, an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema (swelling primarily in the facial area, of lips, eyelids or genitals) or urticaria;
- you have just had major surgery;
- you have certain hereditary blood formation disorders (e.g. acute intermittent porphyria);
- you have an infection - please see heading "Infections" below.

Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. When gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2), and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also patients requiring concomitant low-dose acetylsalicylic acid, or other medicines likely to increase gastrointestinal risk.
If you previously had gastrointestinal toxicity, particularly when elderly, you should report any unusual abdominal symptoms (especially gastrointestinal bleeding), particularly in the initial stages of treatment to your doctor.

Anti-inflammatory/pain-killer medicines like dexibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking <X> if you:
- have heart problems including heart failure, angina pectoris (chest pain), or if you 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 kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Very rarely, severe acute hypersensitivity reactions (e.g. anaphylactic shock with symptoms like shortness of breath, wheezing and drop of blood pressure) have been observed. Stop treatment immediately at the first signs of hypersensitivity reaction after taking <X> and tell immediately your doctor.

You can get a headache if you take high doses of painkillers for a long time (off label use). In this case ask your doctor for advice; you must not take more <X> for the headache.
In general, the habitual use of analgesics, especially with combinations of more than one pain killing active substance, may lead to permanent kidney damage including the risk of kidney failure (analgesic nephropathy).

Skin reactions
Serious skin reactions have been reported in association with <X> treatment. You should stop taking <X> and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Infections
<X> may hide signs of infections such as fever and pain. It is therefore possible that <X> 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 a varicella zoster infection (chickenpox).

Other medicines and <X>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<X> may affect or be affected by some other medicines. For example:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine, rivaroxaban, apixaban or dabigatran) may prolong bleeding time.
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, Angiotensin-II-receptor antagonists such as losartan).
- voriconazole and fluconazole (CYP2C9 inhibitors), used for fungal infections, since the effect of dexibuprofen may increase.

Some other medicines may also affect or be affected by the treatment of <X>. You should therefore always seek the advice of your doctor or pharmacist before you use <X> with other medicines. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

You should **not** take the following medicines with <X> unless you are under close medical supervision:

- Non-steroidal anti-inflammatory drugs (medicines for pain, fever and inflammation). There is an increased risk of ulcers and bleedings in the digestive system if you take <X> with other NSAIDs or acetylsalicylic acid as a pain killer.

You **may** take the following medicines but for safety reasons you should tell your doctor:
- Lithium used to treat certain mood disorders. <X> can increase the effect of lithium.
- Methotrexate (a medicine for cancer or rheumatism). <X> can increase the side effects of methotrexate.
- Diuretics (water tablets), since dexibuprofen may diminish the effects of these medicines.
- Corticosteroids: The risk for gastrointestinal ulcers and bleeding may increase.
- Certain antidepressants (selective serotonin reuptake inhibitors) may increase the risk for gastrointestinal bleeding.
- Digoxin (a heart medicine). <X> can increase the side effects of digoxin.
- Immune suppressants (like ciclosporin, tacrolimus, sirolimus), sulfonylurea (certain oral anti-diabetic medicines) and aminoglycoside antibiotics (medicines to treat infections) - kidney damage may occur.
- Quinolone antibiotics, since the risk for convulsions may be increased.
- Potassium sparing diuretics, since this may lead to high potassium levels in the blood.
- Phenytoin used to treat epilepsy. <X> may increase the side effects of phenytoin.
- Pemetrexed (a medicine to treat certain forms of cancer).
- Zidovudine (a medicine to treat HIV/AIDS); dexibuprofen may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling.
- Baclofen (a muscle relaxant): side effects of baclofen may develop after starting dexibuprofen.
- Sulfinpyrazone, probenecid (medicines for gout), since the excretion of dexibuprofen may be delayed.

<X> with food, drink and alcohol
You may take <X> 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.
You should limit or avoid drinking alcohol when you are taking <X> as this may increase gastrointestinal problems

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

You must not take <X> in the last 3 months of pregnancy, as this may seriously harm your unborn baby, even at very low doses.
In the first 6 months of pregnancy you should only use <X> after consulting your doctor.

You also should not take <X> if you plan to become pregnant, as the medicine may make it more difficult to become pregnant.
In rare cases, drugs such as <X> can affect a woman's fertility. Your fertility will return to normal when you stop taking <X>.

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

Driving and using machines
If you have side effects like dizziness, tiredness, vertigo or if you have a blurred vision after taking <X>, you should avoid driving or using any dangerous machines (see section 4 'Possible side effects').

3. How to take <X>

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

You should take <X> with a glass of water or some other liquid. <X> 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.

Do not take more than **1** <X> tablet for **a single dose**.
Do not take more than **4** <X> tablets **a day**.

For osteoarthritis
The recommended dose is 1 <X> tablet 2 to 3 times a day. For acute symptoms, your doctor may increase the dose to 4 <X> tablets a day.

For period (menstrual) pain
The recommended dose is 1 <X> tablet 2 to 3 times a day.

For mild to moderate pain
The recommended dose is 1 <X> tablet 2 times a day. If higher doses are needed, your doctor may prescribe up to 4 <X> tablets a day.

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).

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

Elderly patients
If you are over 60 years old, your doctor may have prescribed a lower dose than normal. If you are not having problems taking <X>, your doctor may increase your dose.
Use in children and adolescents
As there is not enough experience in children and adolescents, <X> should not be used below the age of 18.

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

If you take more <X> than you should
If you have taken more tablets, than you should, or if children have taken this medicine by accident always contact your doctor straight away or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, ataxia, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low blood pressure, cold body feeling, and breathing problems have been reported.

If you forget to take <X>
Do not take a double dose to make up for a forgotten tablet. Take the next tablet as usual.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Elderly people using this medicine are at increased risk of developing problems associated with side effects.
Side effects are mostly dose-dependent and vary from patient to patient, especially the risk of occurrence of gastrointestinal side effects is dependent on the dosage range and duration of treatment.

Stop taking <X> and seek immediate medical help,
- if you have a severe stomach ache, especially when you start taking <X>.
- if you have black stool, bloody diarrhoea 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 breathe (angioedema) resp. an aggravated asthma.
- if you pass less urine than normal, have swellings, cloudy urine or generally feeling miserable as these could be first signs of kidney damage or kidney failure.

Very common: may affect more than 1 in 10 people
- Gastrointestinal complaints, such as abdominal pain, feeling sick and indigestion, diarrhoea, wind (flatulence), constipation, heart burn, vomiting and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Common: may affect up to 1 in 10 people
- Gastrointestinal ulcers, sometimes with bleeding and perforation (see section 2), black stool (melaena), blood-stained vomit (haematemesis), mouth ulcers and inflammation (ulcerative stomatitis), inflammation of the colon (colitis), worsening of inflammatory bowel disease, complications of colonic diverticula (perforation, fistula).
- Central nervous disturbances such as headaches, dizziness, insomnia, agitation, irritability or sleepiness (somnolence), vertigo, tiredness (fatigue).

Uncommon: may affect up to 1 in 100 people

- Gastritis
- Visual disturbances
- Hypersensitivity reactions such as nettle rash (urticaria), itching, purple bruises (purpura) and exanthema as well as asthma attacks (possibly with drop in blood pressure)
- Swelling of the face or throat (angioedema)
- Anxiety
- Ringing in the ears (tinnitus)
- Runny nose (rhinitis)
- Skin rashes
- Development of oedema especially in patients with arterial hypertension or kidney problems including inflammation of the kidneys and kidney failure

Rare: may affect up to 1 in 1,000 people
- Psychotic reaction
- Vision loss (toxic amblyopia)
- Impaired hearing
- Kidney damage (papillary necrosis), elevated urea concentrations in the blood and elevated uric acid concentrations in the blood
- Liver function problems (usually reversible)
- Depression, confusion, hallucination.

Very rare: may affect up to 1 in 10,000 people
- Difficulty in breathing (predominantly in patients with bronchial asthma),
- Inflammation of the oesophagus or pancreas, formation of membrane-like narrowing in the small and large intestines (intestinal, diaphragm-like strictures)
- Oedema, high blood pressure, inflammation of the blood vessels, palpitations, heart failure
- Liver dysfunction, liver damage, especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis) and jaundice
- Photosensitivity reactions
- Problems in the blood cell production (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis) - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In these cases you must stop the therapy immediately and consult a doctor. You must not treat these symptoms with pain killers or medicinal products that reduce fever (antipyretic products)
- Worsening of infection-related inflammations (e.g. necrotising fasciitis) associated with use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of dexibuprofen, go to a doctor without delay to investigate whether there is a need for an anti-infective/antibiotic therapy
- Exceptionally, severe skin infections and soft-tissue complications during chicken pox (varicella) infection
- Symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness clouding have been observed when using dexibuprofen. Patients with autoimmune disorders (SLE, mixed connective tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur
- Severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia)
- Severe general hypersensitivity reactions (face, tongue and larynx oedema, dyspnoea, tachycardia, hypotension, severe shock), aggravated asthma

Not known (frequency cannot be estimated from the available data)
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using <X> if you develop these symptoms and seek medical attention immediately. See also section 2.

Medicines such as <X> 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 the national reporting system listed in Appendix V*. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <X>

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.
Do not use this medicine after the expiry date which is stated after "EXP:" on the carton and on the blister.
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 <X> contains
- The active substance is dexibuprofen. One film-coated tablet contains 300 mg dexibuprofen.
- The other ingredients are
  Tablet: Hypromellose, microcrystalline cellulose, carmellose calcium, colloidal anhydrous silica, talc.
  Film coating: Hypromellose, titanium dioxide (E171), triacetin, talc, macrogol 6000.

What <X> looks like, and the contents of the pack
The 300 mg tablets are white, round tablets
Diameter: approx. 11.2 mm
Height: approx. 5.2 mm

<X> tablets are supplied in boxes of 10, 20, 30, 50, 60, 90 and 100 tablets in transparent, colourless PVC/PVDC/aluminium blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

<[To be completed nationally]>

This product is authorised in the Member States of the EEA under the following names:

Austria:	Dexibuprofen "Gebro" 300 mg Filmtabletten
Portugal:	Seractil 300 mg comprimidos revestidos
Sweden:	Tradil 300 mg filmdragerade tabletter
Denmark:	Seractiv 300 mg filmovertrukne tabletter
Greece:	Seractil 300 mg film-coated tablets
Italy:	Seractil 300 mg compresse rivestite con film

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