

PACKAGE LEAFLET

Package leaflet: Information for the patient

Oprixxa 500 mg/150 mg film-coated tablets

Paracetamol/Ibuprofen

<[Prescription only:]>

<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.>

<[Non-prescription:]>

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after X days.>

<[To be completed nationally]>

What is in this leaflet

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

1. What /.../ is and what it is used for

/.../ contains both paracetamol and ibuprofen.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness) and reduces fever. Paracetamol is an analgesic which relieves pain and reduces fever.

/.../ is used for temporary relief of acute pain such as headache (not migraine), backache, dental pain, muscular pain and sore throat. /.../ is also used for fever.

<[Non-prescription:]><You should talk to a doctor if the symptoms persist for more than X days or worsen, or if the product is required for more than X days.>

2. What you need to know before you take /.../

Do not take /.../:

- if you are allergic to paracetamol and/ or ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you have or have had any gastrointestinal bleeding which can be shown as bleeding from the back passage, black sticky stools or bloody diarrhoea;
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before;
- if you have had asthma, hives, or allergic-type reactions after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs);
- if you regularly drink large quantities of alcohol;
- if you have severe kidney or liver failure;
- if you have severe heart failure;
- if you have bleeding in the brain or other active bleeding;
- if you have problems with blood formation and an increased tendency to bleed;
- during the last three months of pregnancy

Warnings and precautions

Anti-inflammatory/pain-killer medicines like ibuprofen 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 /.../ if you:

- have heart problems including heart failure, angina (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.

Talk to your doctor or pharmacist before taking /.../

- you have liver disease or kidney disease or if you are dehydrated;
- you are taking other painkilling medicine, including paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) and acetylsalicylic acid as this may increase the risk of serious side-effects;
- you are elderly (over 65 years old), since there is an increased risk of side effects;
- you currently have chicken pox;
- you have porphyria;
- you have an infection - please see heading “Infections” below;
- you have or have had other medical conditions including:
 - heartburn, indigestion, stomach ulcer or any other stomach problems;
 - severe skin reactions such as Stevens-Johnson syndrome (SJS) or toxic epidermal necrosis (TEN);
 - asthma;
 - tendency to bleed or other blood problems;
 - bowel or intestinal problems such as ulcerative colitis or Crohn’s disease;
 - swelling of ankles or feet;
 - autoimmune disease such as systemic lupus erythematosus (SLE);

During treatment with /.../, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to

organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Skin reactions

Serious skin reactions have been reported in association with Opixxa treatment. You should stop taking Opixxa 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.

Prolonged or frequent use of pain relieving medication can cause headaches which should not be treated by increasing the dose. If this happens, stop taking the medication and consult your doctor.

Never take more of /.../ than recommended. A higher dose does not increase pain relief; instead it can cause serious liver damage. The symptoms of liver damage occur first after a few days. It is therefore very important that you contact your doctor as soon as possible if you have taken more /.../ than recommended in this leaflet.

Do not use /.../ without a doctor's prescription if you have alcohol problems or liver damage and do not use /.../ together with alcohol. The intoxicating effect of alcohol does not increase by taking /.../.

Tell your doctor that you are using /.../ if your doctor orders a urine test, since this medicine can cause an incorrect test response in some tests.

Infections

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

Children and adolescents

/.../ should not be used in children and adolescents under 18 years.

Other medicines and /.../

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

/.../ may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines to treat epilepsy or fits (e.g. phenytoin, phenobarbital, carbamazepine)
- chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout
- zidovudine a medicine used to treat HIV (the virus that causes AIDS)
- medicines used to treat tuberculosis such as isoniazid and rifampicin
- acetylsalicylic acid, salicylates or other NSAID medicines
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

- medicines to treat heart conditions (e.g. digoxin or beta blockers)
- mifepristone, a medicine used for medical termination of a pregnancy
- diuretics, also called fluid tablets
- medicines used to treat mania or depression (e.g. lithium or SSRIs)
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- anti sickness medicines (e.g. metoclopramide and domperidone)
- medicines for high cholesterol (e.g. Cholestyramine)
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas: medicines used to treat diabetes
- a type of antibiotic known as aminoglycosides
- antifungal medicines such as voriconazole or fluconazole
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

Your doctor and pharmacist will have more information about these medicines and how to act.

Some other medicines may also affect or be affected by the treatment of /.../. You should therefore always seek the advice of your doctor or pharmacist before you use /.../ with other medicines.

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor (see also section “Warnings and precautions”).

/.../ with alcohol

Do not use /.../ without a doctor’s prescription if you have alcohol problems or a liver damage and do not use /.../ together with alcohol. The intoxicating effect of alcohol does not increase by taking /.../.

Pregnancy, breast-feeding and fertility

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

Pregnancy

Do not take /.../ 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 /.../ 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, /.../ 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.

Breast-feeding

/.../ may be used during breast-feeding if used for short term treatment at the recommended dose.

Fertility

<[Prescription only:]>

/.../ may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

<[Non-prescription:]>

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

/.../ may cause dizziness, drowsiness, fatigue and visual disturbances in some people. This should be taken into consideration on occasions when high alertness is required, e.g. driving. Be careful driving or operating machines until you know how /.../ affects you.

/.../ contains Lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take /.../

<[Prescription only:]>

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

<[Non-prescription only:]>

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

/.../ is for short term use only

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).

Higher doses than recommended may lead to serious risks.

Adults: The recommended dose is 1 to 2 tablets taken every 6 hours, as required.

Do not take more than 8 tablets in a 24 hours period.

Take /.../ tablets with or without food with a full glass of water.

The score-line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Elderly: There is no indication that the dosage needs to be modified in the elderly, but if you are elderly you may be more prone to serious side effects, especially bleeding and perforation in the digestive tract.

Liver or kidney problems: If you have liver or kidney problems, your dose may need to be reduced or the time between doses increased, so ask your doctor for advice.

If you take more /.../ than you should

If you have taken more /.../ than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. Do this even if there are no signs of discomfort or poisoning.

Taking too many /.../ tablets can lead to delayed, serious liver damage which may be fatal. You may need urgent medical attention.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally

patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Decreased body temperature (hypothermia) has been reported after taking ibuprofen in overdoses, but also at recommended doses.

If you forget to take /.../

If it is almost time for your next dose, skip the dose missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose that you missed.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Always leave at least 6 hours between doses

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. If you get any side effects, talk to your doctor or pharmacist.

If any of these serious side effects happen, stop taking /.../ and tell your doctor immediately or go to the emergency room at your nearest hospital:

Uncommon (may affect up to 1 in 100 people):

- vomiting blood or material that looks like coffee grounds. Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea. These can all be signs of intestinal bleeding;
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing. Sudden or severe itching (pruritus), skin rash, hives (urticaria). These can all be signs of a severe allergic reaction;

Very Rare (may affect up to 1 in 10,000 people):

- asthma, wheezing, shortness of breath.

Very rare cases of serious skin reactions have been reported.

Not known (frequency cannot be estimated from the available data)

- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck. These can be signs of inflammation of the brain lining.
- decreased body temperature (hypothermia).
- 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 Opirxxa if you develop these symptoms and seek medical attention immediately. See also section 2.

Other side effects:

Common (may affect up to 1 in 10 people):

- changes in liver or kidney function (established by blood tests)

- ringing in the ears (tinnitus)
- nausea or vomiting
- heartburn or stomach pain
- cramps, bloating, flatulence, stomach discomfort, constipation or diarrhoea
- skin rashes, itching, swelling of the lips, eyes, hands or feet
- vertigo
- fatigue, agitation, irritability, nervousness
- headache, dizziness
- fluid retention and swelling, which usually responds to stopping the treatment

Uncommon (may affect up to 1 in 100 people):

- peptic ulcer, gastrointestinal bleeding, abdominal pain (gastritis)
- inflammation of the lips and mouth (stomatitis)
- worsening of existing ulcerative colitis or Crohn's disease
- inflammation of the pancreas (pancreatitis)
- difficulty urinating
- changes in the numbers of red or white blood cells or other changes to blood composition or acidity (established by blood tests)
- breast enlargement (in males)
- abnormally low blood sugar (hypoglycaemia)
- change in mood, for example depression, confusion, emotional instability, insomnia, sleepiness
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- allergic reactions
- eye problems such as blurred vision, changes in colour vision or blind spots
- fast or slow heart rate
- skin reactions and sensitivity to light
- kidney problems causing increased or decreased urination, swelling of the legs, blood in the urine or pain in the side of the abdomen
- hair loss.

Rare (may affect up to 1 in 1,000 people):

- tingling of the hands and feet
- abnormal dreams, hallucinations

Very Rare (may affect up to 1 in 10,000 people):

- movement problems such as inability to keep still or inability to start and control movement
- anxiety and restlessness
- uncontrolled shaking or convulsions (fits)
- intestinal blockage
- flesh-eating infection, unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- excessive sweating
- fast or irregular heartbeats, also called palpitations
- heart failure, heart attack, high blood pressure or low blood pressure
- kidney failure
- liver problems and yellowing of the skin and /or eyes, also called jaundice

Not known (frequency cannot be estimated from the available data)

- a serious condition that can make blood more acidic (called metabolic acidosis), in patients

with severe illness using paracetamol (see section 2)

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 <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

Keep this medicine out of the sight and reach of children and adolescents.

Store below 30 °C.

Store in the original package in order to protect from light.

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 /.../ contains

- The active substances are paracetamol and ibuprofen. Each film-coated tablet contains 500 mg of paracetamol and 150 mg of ibuprofen.
- The other ingredients are: maize starch, pre-gelatinised maize starch, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, talc. Tablet coating: HPMC 2910/Hypromellose 15cP (E464), Lactose monohydrate, Titanium dioxide (E171), Macrogol/PEG-4000, Sodium citrate-dihydrate (E331)

What /.../ looks like and contents of the pack

/.../ film-coated tablets are white, capsule shaped, film-coated tablets, 19mm in length, with score-line on one side and plain on the other side.

They come in blister packs containing 8, 10, 12, 16, 20, 24, 30, 32, 50 or 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<[to be completed nationally]>

Manufacturer:

<[to be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in

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