



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

TABUFEN 200 CAPSULE

Ibuprofen 200mg Capsule

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
If you have any further questions, ask your health care provider.
This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

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

1. WHAT TABUFEN CAPSULE IS AND WHAT IT IS USED FOR

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which act to relieve pain and reduce swelling. It can be used to relieve headaches, rheumatic and muscular pain, pain from non-serious arthritic conditions, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TABUFEN CAPSULE

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take TABUFEN CAPSULE if:

- Have a stomach ulcer, perforation, or bleeding, or have had one twice or more in the past
Have had perforation or a bleeding stomach after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
Are allergic to ibuprofen or any other ingredients of the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
Are taking aspirin with a daily dose above 75 mg, or other non-steroidal anti-inflammatory medicines
Have severe heart, kidney or liver failure
Have an intolerance to some sugars, unless your doctor tells you to (this medicine contains lactose)
Are pregnant, and in the last 3 months of pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before taking Tabufen Capsules.

- Are elderly, as you may be more likely to suffer from side effects
Have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
Are allergic to any other painkiller
Suffer from systemic lupus erythematosus (a chronic rheumatic disease)
Suffer from an allergy
Suffer from inflammation of the intestines (ulcerative colitis, Crohn's disease)
Are on low-dose aspirin (up to 75 mg daily)
Are a smoker
Are in the first 6 months of pregnancy
If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted
Have an infection - please see heading "Infections" below.

If you have heart problems, previous stroke or think 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.

Infections

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

Other medicines and Tabufen Capsule

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

Other medicines and Tabufen Capsules

If you are taking any of the following medicines, please see your doctor before taking the capsules:

- Any other painkillers (aspirin or other NSAIDs). Do not take this medicine if you are taking aspirin at doses of above 75mg daily. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take Tabufen Capsule.
Regular medication for high blood pressure (antihypertensives or diuretics)
Blood thinner medicines (anti-coagulants)
Corticosteroids (anti-inflammatory) which can increase the risk of side effects in the stomach including bleeding
Anti-platelet agents (prevention of thrombotic cerebrovascular and cardiovascular diseases)
Serotonine reuptake inhibitors and lithium (for treatment of depression - bipolar disease and mania)
Cardiac glycosides (treatment of heart failure and cardiac arrhythmia)
Methotrexate (anti-cancer and psoriasis)
Zidovudine (HIV/AIDS infection)
Cyclosporine (prevent rejection after organ transplant)
Mifepristone (emergency contraceptive)
Tacrolimus (prevent rejection after organ transplant, treatment of skin diseases)
Quinolone (antibiotics)

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan), and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek advice of your doctor or pharmacist before you take ibuprofen with other medicines.

Pregnancy, breast-feeding 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.

Pregnancy and breast-feeding

Ask your doctor or pharmacist before taking this medicine if you are in the first 6 months of pregnancy. DO NOT TAKE the capsules if you are in the last 3 months of pregnancy. Ask your doctor or pharmacist for advice before taking any medicine if you are breast-feeding.

Fertility

Tabufen Capsule belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Tabufen Capsule used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

Tabufen Capsule are unlikely to cause any effect on your ability to drive or use machines.

3. HOW TO TAKE TABUFEN CAPSULES

Use in children

Not suitable for children under 12 years.

For oral administration and short-term use only

Dosage: Adults, the elderly, and children and adolescents over 12 years of age: The minimum effective dose should be used for the shortest time necessary to relieve symptoms. 1 or 2 capsules every 4-6 hours, as required. The capsules

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Table with 4 columns for signature and date. Headers: Prepared By, Approved by, Signature, Date, Designation. Designations: AMRA, HoM, HQRA.



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should be taken with water. Take only as much as you need and leave at least 4 hours between each dose.

Do not take more than 6 capsules in any 24-hour period.

If you are aged between 12 and 18 years and the product is required for more than 3 days or if the symptoms worsen, you should contact your doctor.

If you are 18 years or older you should not take this product for longer than 10 days unless your doctor tells you to.

If symptoms persist or worsen consult a pharmacist or your doctor. 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.

If you take more Tabufen Capsule than you should

If you have taken more capsules than you should, or if children have been taken medicine by accident always contact a doctor 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, 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, cold body feeling, and breathing problems have been reported.

If you forget to take Tabufen Capsule:

Do not take a double dose to make up for a forgotten dose. If you have any question on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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.

If you suffer from any of the following, at any time, during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
• Pass black tarry stools
• Vomit any blood or dark particles that look like coffee grounds

STOP taking the medicine and tell your doctor if you experience:

- Indigestion or heartburn
• Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
• Skin problems

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

If you experience any of the following side effects, or anything unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

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

- Itchy skin or rashes, urticaria (hives)
• Abdominal pain, nausea (feeling sick), stomach and bowel problems
• Headache

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

- Diarrhoea, wind (flatulence), constipation and vomiting

Very rare (may affect up to 1 in 10,000 people) side effects are:

- Kidney failure, liver problems, problems in the blood cell production:
• The first signs can be fever, sore throat, mouth ulcers, flu like symptoms, severe exhaustion, unexplained bleeding and bruising
• Meningitis (inflammation of the membrane around the brain) symptoms such as fever and chills, severe headache, nausea and vomiting and stiff neck (in patients with inflammatory disease of connective tissue in the skin or joints (systemic lupus

- erythematousus) ,
• Peptic ulcer, perforation or stomach and intestinal bleeding (gastrointestinal haemorrhage), black tarry stools, vomit of blood or dark particles, inflammation of the mouth (ulcerative stomatitis), inflammation of the stomach (gastritis)
• Low blood pressure (hypotension)
• Fast heart rate (tachycardia)
• Life threatening allergy (anaphylaxis)
• Facial or tongue or larynx swelling
stomach ulcer
• Severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-johnson syndrome, skin peeling (toxic epidermal necrolysis)
• Kidney damage (papillary necrosis) resulting in increased urea concentration in the blood and swelling (oedema)
• Decreased haemoglobin (a blood protein) levels

Side effects with frequency not known:

- Swelling (oedema), high blood pressure (hypertension) and heart failure
• Worsening of colitis or crohn's disease (inflammation of the bowel)
• Worsening of asthma (difficulty in breathing) unexplained wheezing or shortness of breath
• Skin becomes sensitive to light
• Skin problems:
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 Tabufen Capsule if you develop these symptoms and seek medical attention immediately. See also section 2.

5. HOW TO STORE TABUFEN CAPSULE

- Keep all medicines out of the sight and reach of children
• Do not take this medicine after the expiry date which is stated on the label after "EXP" The expiry date refers to the last day of that month.
• Store below 30 °C.
• Store in the original container.

6. FURTHER INFORMATION.

Each Tabufen 200 Capsule contains 200mg of Ibuprofen 200mg

What TABUFEN CAPSULE looks like and contents of the pack

Capsules packed in a 10 X 10 blisters and placed in an inner carton with insert.

SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc,
Km.38, Lagos-Abeokuta Expressway,
Sango-Ota, Ogun State, Nigeria
234-(0)8077008888
Customercare@fidson.com

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