

PATIENT INFORMATION LEAFLET

Ibuprofen Oral Suspension BP 100mg/5ml- SKYBRU

Read all of this leaflet carefully before you start taking this medicine.

- 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 or your child. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT SKYBRU IS AND WHAT IT IS USED FOR

SKYBRU contains Ibuprofen BP as active pharmaceutical ingredient. They belong to a group of medicines called anti-malarials.

Symptomatic treatment of painful conditions of mild to moderate and/ or fever.

2. BEFORE YOU TAKE OR GIVE SKYBRU .

Do not take SKYBRU and tell your doctor if:

- you are sensitive (allergic) to any of the ingredients in the suspension. These are listed in Section 6
- you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past
- you suffer from severe heart failure
- you are sensitive (allergic) or previously had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers

Take special care with SKYBRU if:

- you have, or previously suffered from asthma
- you suffer from liver, kidney or heart disease

- you suffer from high blood pressure (hypertension)
- you are elderly – elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- you have been told by your doctor that you have an intolerance to some sugars
- you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint
- you have a history of inflammatory bowel disease (ulcerative colitis, Crohn's disease)
- you are dehydrated
- you have a condition which increases your tendency to bleeding or have bleeding in the skull
- you have lupus or a connective tissue disease (autoimmune diseases affecting connective tissue)

If any of these apply to you, please tell your doctor or pharmacist BEFORE taking SKYBRU:

SKYBRU 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 becoming pregnant

Medicines such as **SKYBRU** may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other Medicines

Can you take SKYBRU with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. Aspirin /acetylsalicylic acid, warfarin, ticlodipine), 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 the advice of your doctor or pharmacist before you use ibuprofen 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:

- any medicines used to treat high blood pressure (see above)
- any medicines to treat heart conditions (e.g. diuretics such as bendroflumethiazide or furosemide or cardiac glycosides such as digoxin)
- any anti-coagulants or anti-platelet medicines (see above)
- lithium or selective serotonin reuptake inhibitors (SSRIs) (used to treat depression)
- a medicine called zidovudine (an anti-viral drug)
- a medicine called methotrexate (used to treat some forms of cancer)
- medicines called ciclosporin or tacrolimus (immunosuppressants used following organ transplant or in autoimmune conditions such as psoriasis, eczema)
- any other NSAIDs or anti-inflammatory pain killers, including aspirin and the group of drugs known as COX-2 inhibitors such as celecoxib and lumiracoxib
- any corticosteroids (e.g. hydrocortisone, betamethasone, prednisolone, used to treat inflammatory conditions)
- a certain type of antibiotic, known as quinolone antibiotics (e.g. ciprofloxacin and levofloxacin)
- probenecid (used to treat gout)
- a certain type of antibiotic known as aminoglycosides
- mifepristone (now or in the last 12 days)
- any oral medicines used to treat diabetes (e.g. metformin, or any sulphonamides)
- a herbal remedy called ginkgo bilboa (there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time).

Pregnancy and breast-feeding:

Please tell your doctor if you are, or think you are, pregnant. **SKYBRU** should be avoided during pregnancy and breast feeding and should not be used in late pregnancy (the last three months).

Driving and Using Machines:

SKYBRU is not known to cause any effect on the ability to drive or use machines.

What else do you need to know about SKYBRU?

Do not take **SKYBRU** if you are allergic to aspirin. If you develop an unexpected skin rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine, stop taking it and contact your doctor for advice. Some of the ingredients in **SKYBRU** may cause allergic reactions – please refer to the section “Possible side effects of **SKYBRU**”.

3.HOW TO TAKE SKYBRU

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

Taking SKYBRU

SKYBRU Suspension may be taken on an empty stomach with a little water. However, a small number of people may experience mild indigestion with **SKYBRU**. If this happens to you, it may help if you take the medicine with some food or milk.

Remember to shake the bottle before use.

How much to take

Adults: The usual dose is four to six 5 ml spoonful taken three times each day. Your doctor may choose to increase or decrease this dose depending on your symptoms, but no more than 120 ml of Oral suspension (2400 mg) should be taken each day.

Children: The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses.

This can be given as follows:

1-2 years 2.5 ml three to four times a day

3-7 years One 2.5-5 ml three to four times a day

8-12 years 10 ml three to four times a day

The doctor may choose to increase this dose in children with severe arthritis, if needed. In children weighing less than 30 kg, no more than 500 mg of **SKYBRU** should be given each day.

Elderly: – Refer to adult dosing. If you have liver or kidney problems however, your dose may need to be modified in which case you should contact your doctor for advice.

How long to take it

Continue taking your medicine until you finish the pack or for as long as your doctor recommends.

For treating infections, this medicine is usually taken for one to two weeks. However, your doctor may prescribe it for longer periods.

Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear up completely or your symptoms may return.

Check with your doctor if you are not sure how long you should be taking SKYBRU

If you forget to take it

If it is almost time for your next dose, skip the dose you 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 medicine as you would normally.

Do not take a double dose to make up for the dose that you have missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much erythromycin. Do this even if there are no signs of discomfort or poisoning.

4.POSSIBLE SIDE EFFECTS

As with all medicines, **SKYBRU** may cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimize the risk of side effects by taking the least amount of medicine for the shortest amount of time necessary to control your symptoms.

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

- Severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING THE MEDICINE IF YOU EXPERIENCE:

- Hypersensitivity reactions such as unexplained wheezing, shortness of breath, skin rash, itching or bruising
- Unexplained stomach pain or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever
- Blurred or disturbed vision or seeing/hearing strange things
- Fluid retention (e.g. swollen ankles).

Medicines such as **SKYBRU** have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Very rarely **SKYBRU** may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain). **SKYBRU** may hide the signs of an underlying infection.

Other side effects of **SKYBRU** may include:

- nausea, vomiting, diarrhoea, flatulence (wind), constipation, stomach ache
- mouth ulcer
- increase in severity of Crohn's disease or colitis
- inflammation of the stomach lining
- inflammation of the pancreas
- burning sensation in the mouth or throat
- high blood pressure (hypertension)
- heart failure
- blood disorders such as a reduction in different types of cells in the blood depression, confusion, seeing or hearing things that are not really there (hallucinations) headaches, numbness or tingling, dizziness, drowsiness, tiredness, generally feeling unwell
- blurred or disturbed vision, inflammation of the optic nerve
- balance disorder which makes you feel unsteady, giddy, woozy, or have a sensation of movement,
- spinning, or floating (vertigo), ringing in the ears
- liver problems such as hepatitis or jaundice
- skin problems such as increased sensitivity to light and severe reactions (such as blistering of the skin, mouth, eyes and genitals)
- kidney problems, including reduced kidney function and kidney failure

SKYBRU contains the colouring agent Sunset Yellow which may cause allergic reactions.

SKYBRU contains Methyl parahydroxybenzoate and Propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

SKYBRU contains 3.3g of sucrose per 5ml does. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth

5. HOW TO STORE SKYBRU

Keep this medicine in a safe place where children cannot see or reach it.

Do not use **SKYBRU** after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. After use , wipe the neck of the bottle with clean, damp cloth. This will remove any medicine left on the bottle, so you can put the measuring beaker is clean and dry before use it.

Store in cool place, below 30°C.

Protect from light.

SHAKE WELL BEFORE USE as it a suspension.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. The measures will help to protect the environment

6. FURTHER INFORMATION

What SKYBRU contains

- The active substances of SKYBRU is Ibuprofen.
- The other ingredients are Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Citric Acid Monohydrate, Sucrose , Saccharin Sodium, Glycerol , Microcrystalline Cellulose and Carmellose Sodium, Aluminium Magnesium, Polysorbate 80 , Colour sunset yellow FCF, Flavour Essence vanilla, Flavour Sweet orange, Flavour pineapple.

What SKYBRU looks like and contents of the pack

Light orange coloured, homogenous suspension with characteristic odour and sweet taste.. SKYBRU is available in 100 ml pack

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

Eskay Therapeutics Ltd.

42, South Industrial Area,

Accra, Ghana

Tel.: +233 30 2241509 / 2251725

Manufacturing Site

S Kant HEALTHCARE Ltd.

PLOT NO. 1802-1805, G.I.D.C. PHASE III,

VAPI 396 195, GUJARAT,

INDIA.

Tel: 91-260-6549517

Fax: 91-260-2430527