1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

IBUMOL GRAPE

Suspension

Read all of this leaflet carefully because it contains important information for you

IBUMOL GRAPE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use IBUMOL GRAPE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IBUMOL GRAPE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

WHAT IBUMOL GRAPE CONTAINS

The active substances are ibuprofen and paracetamol.

Each 10 ml of IBUMOL GRAPE contains 200 mg of ibuprofen and 250 mg of paracetamol.

The other ingredients are brilliant blue (C.I. 42090), carbopol, carmoisine (C.I. 14720), flavour grape, flavour tutti-frutti, glycerol, polysorbate, purified water, sodium metabisulphite, saccharin sodium, sodium benzoate, sodium cyclamate and sorbitol (70 %) solution.

Preservative:

Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol 3,26 g, glycerol 630,5 mg

Contains sweetener: Sodium cyclamate 50 mg, saccharin sodium 7 mg

WHAT IBUMOL GRAPE IS USED FOR

IBUMOL GRAPE is indicated for the short-term relief of mild to moderate pain of inflammatory origin with or without fever in children.

BEFORE YOU OR YOUR CHILD TAKE IBUMOL GRAPE

You or your child should not take IBUMOL GRAPE:

- If you are hypersensitive (allergic) to any of the ingredients of IBUMOL GRAPE.
- If you have a history of gastrointestinal bleeding, ulceration or perforation (PUBs) related to IBUMOL GRAPE or to any other NSAIDs treatment.
- If you have an active or history of recurrent gastrointestinal ulcer or haemorrhage or perforations.
- If you have cardiovascular disease, heart, liver or kidney failure.
- If you are sensitive to aspirin or another non-steroidal anti-inflammatory medicines (NSAIDs).
- If you have uncontrolled asthma or bronchospasm.
- If you have nasal polyps associated with aspirin-induced bronchospasm.
- If you are pregnant and in the last trimester of pregnancy.
- If you are receiving warfarin.

Paracetamol:

- If you have severe liver impairment.

Take special care with IBUMOL GRAPE:

Ibuprofen

- If you have a history of hypertension and/or heart failure as fluid retention and oedema (abnormal swelling from an accumulation of fluid beneath the skin) have been reported in association with IBUMOL GRAPE therapy.
- If you suffer from SLE (a systemic autoimmune disease) or a similar condition.
- If you have impaired liver or kidney function.
- If you have a pre-existing disorders of blood coagulation (clotting) or anaemia (lower than normal number of red blood cells).
- If your treatment is prolonged your doctor should do regular blood counts and monitor your liver and kidney function. Depending on the results, your doctor may decide to discontinue your treatment.
- If you are an elderly patient, especially if you are a frail patient or have a low body mass (weight), your doctor may reduce your dosage.
- If you have a history of gastrointestinal (stomach) disease (e.g. ulcerative colitis (a form of bowel disease), Crohn's disease (inflammatory disease of the bowel and digestive tract), hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia (unexplained bleeding in the stomach) as the condition may be exacerbated.
- If you have serious skin reactions, which may be fatal, including exfoliative dermatitis (inflammatory skin disease), Stevens-Johnson syndrome, and toxic epidermal necrolysis (where the top layer of skin detaches from the lower layers) have been reported.

IBUMOL GRAPE should be discontinued at the first appearance of skin rash, mucosal lesions (sores), or any other sign of hypersensitivity or adverse reaction.

- If you have asthma or any other allergic condition.

Paracetamol

- If you have impaired (weakened) kidney or liver function.
- If you are dependent on alcohol.

Pregnancy and breastfeeding

IBUMOL GRAPE should not be used during the last trimester of pregnancy.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking IBUMOL GRAPE.

Driving and using machinery

Dizziness, drowsiness, fatigue and visual disturbances are possible after taking IBUMOL GRAPE. If you experience any of these effects you should not drive or operate machinery.

Important information about some of the ingredients in IBUMOL GRAPE

IBUMOL GRAPE contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take IBUMOL GRAPE.

Taking other medicines with IBUMOL GRAPE

Always tell your healthcare provider if you are taking any other medicine (this includes

complementary or traditional medicines).

The use of IBUMOL GRAPE together with the following medicines may cause bad effects:

Ibuprofen

- Antiplatelet and anticoagulants (blood thinning tablets) such as aspirin or warfarin.
- Medicines to treat diabetes.
- Antihypertensives, beta blockers and diuretics.
- Aminoglycoside antibiotics.
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin or tacrolimus (used to treat some inflammatory diseases and after transplants).
- Quinolone antibiotics (for infections).
- Digoxin used to treat heart problems.
- Medicines known as SSRIs used to treat depression.
- Oral steroids (an anti-inflammatory medicine).
- Another non-steroidal anti-inflammatory medicine.
- Mifepristone, a medication used in abortion.
- Zidovudine a medication used in HIV.
- Bone marrow depressants.
- The risk of gastrointestinal bleeding and ulceration is increased when used with alcohol, bisphosphonates or oxypentifylline.

Paracetamol

- Enzyme inducing and hepatotoxic medicines (those that destroy liver cells).

- Metoclopramide used as an antiemetic (medicine that relieves nausea and vomiting).
- Cholestyramine used in reducing cholesterol levels in the blood.
- Probenecid used to treat gout.

HOW TO TAKE IBUMOL GRAPE

Always take IBUMOL GRAPE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

SHAKE THE BOTTLE BEFORE USE.

Adults and children over twelve years:

One to two medicine measurefuls (5 ml to 10 ml) four hourly if necessary and not more than six medicine measurefuls in twenty four hours.

Children six to twelve years old:

One to two medicine measurefuls (5 ml to 10 ml) three to four times daily.

Children two to five years old:

Half to one medicine measurefuls (2,5 ml to 5 ml) three to four times daily.

Safety in children under two years of age has not been proven.

IBUMOL GRAPE should be taken with or after food.

Do not use for longer than 10 days.

If you have the impression that the effect of IBUMOL GRAPE is too strong or too weak, tell your doctor or pharmacist.

Use the lowest effective dose for the shortest possible duration of treatment.

If you take more IBUMOL GRAPE than you should

IBUMOL GRAPE contains paracetamol which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take IBUMOL GRAPE

As soon as you remember that you missed taking a dose, take a dose as soon as possible.

If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten dose, take the same amount that you always take.

POSSIBLE SIDE EFFECTS

IBUMOL GRAPE can have side effects.

Not all side effects reported for IBUMOL GRAPE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUMOL GRAPE, please consult your healthcare provider for advice.

If any of the following happens, stop taking IBUMOL GRAPE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions which can include skin rash, itching, bruising, painful red areas peeling or blistering, hypersensitivity reactions;
- wheezing or shortness of breath (bronchospasm);
- swollen face, lips, hands or fingers.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IBUMOL GRAPE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Any sign of bleeding in the stomach or intestine (bowel), for example, when emptying your bowels, vomiting blood or black, tarry faeces;
- yellowing of skin or the whites of your eyes, jaundice;
- aseptic meningitis (inflammation of the tissues that cover the brain and spinal cord) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation;
- heart failure may be precipitated in compromised patients, chest pain and irregular heartbeat;
- peptic ulceration, perforation or gastrointestinal bleeding sometimes fatal;
- impairment of kidney function and kidney failure and fluid retention;
- an unexpected change in the amount of urine produced and/or its appearance.

These are all serious side effects. You may need urgent medical attention.

The following side effects have been frequently reported:

- Dizziness;
- skin rash;
- itching;
- nausea, abdominal cramps and pain;
- indigestion, heartburn, wind, nausea (feeling sick), or vomiting (being sick).

The following side effects have been reported less frequently:

- Inflammation of the nose;
- blood disorders like decrease in white blood cells, decrease in red blood cells;
- confusion, nervousness, sleeplessness, depression, anxiety, hallucination, drowsiness, blurred vision and other ocular (eye) reactions, ringing in the ears;
- indigestion, bloating, constipation, decreased appetite, diarrhoea and inflammation of the pancreas;
- abnormalities of liver function tests, inflammation of the liver;
- blood disorders, like decrease in white blood cells, decrease in red blood cells.

The following side effects have been reported but the frequency is unknown:

- Sensitivity reactions resulting in reversible skin rash;
- kidney pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF IBUMOL GRAPE

Store at or below 25 °C in well-closed containers.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF IBUMOL GRAPE

100 ml is packed into a round, amber glass bottle sealed with a white, tamper evident polypropylene duet screwcap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

100 ml is packed into a natural brown, round, high density polyethylene bottle sealed with a white, low density polyethylene (LDPE), snap-cap closure. The bottle is placed in an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF IBUMOL GRAPE

A homogenous, purple suspension with a sweet, fruity grape odour and flavour and a bitter aftertaste.

REGISTRATION NUMBER

A39/2.8/ 0229

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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