

ASKETON FILM-COATED TABLET

Itopride hydrochloride 50mg

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What ASKETON is used for

Asketon is used in adults to treat:

- Symptoms of gastric dysmotility and delayed gastric emptying such as bloating, early satiety, postprandial fullness, upper abdominal pain or discomfort
- Loss of appetite
- Heartburn
- Nausea and vomiting
- Non-ulcer indigestion
- Chronic gastric inflammation

How ASKETON works

Asketon contains the active substance itopride. Asketon activates stomach motility, antiemetic action and accelerates gastric emptying.

Before you use ASKETON

- When you must not use it

Do not take Asketon if you:

- are allergic to itopride or any of the other ingredients of this medicine
- could be harmful if you have increased stomach motility eg. gastric bleeding, gastric obstruction or perforation

- Before you start to use it

Talk to your doctor before taking Asketon if you:

- are an elderly
- are galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption
- are under age 16
- have liver impairment
- have kidney impairment

Pregnancy and breast-feeding

Tell your doctor if you become pregnant, or you are trying to become pregnant, while you are taking Asketon. You should use Asketon only after discussing the potential benefits and any potential risks to your unborn child with your doctor.

There is possibility of adverse effect to the infant, therefore, speak to your doctor or pharmacist whether to take Asketon or discontinue breast-feeding.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Medicine with narrow therapeutic index
- Medicine with prolonged-release and enteric-coated drug formulation
- Medicine that reduce the spasm of stomach (Anticholinergic agents)

Your doctor should decide whether you can take Asketon with other medicines. Do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor.

How to use ASKETON

- How much to use

Adult

The recommended daily dose is 150 mg (1 tablet 3 times) a day before meal.

Elderly

The dosage should be advised by doctor with adequate precaution

Paediatric population

Use with caution if you are under 16 years old

Kidney or liver impairment

The dose might be reduce or discontinue

- When to use it

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

ASKETON is for oral use. You should take it before meal.

- How long to use it

Asketon should not be used more than 8 weeks. Do not stop taking Asketon, or change your dose, without talking to your doctor.

- If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed

dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of Asketon that has been prescribed for you in one day.

- If you use too much (overdose)

Call your doctor or pharmacist immediately if you take more than the amount of Asketon.

While you are using it

- Things you must do

Tell all doctors, dentists and pharmacists treating you that you are taking Asketon.

- Things you must not do

DO NOT stop taking your tablets without the advice of your doctor even if you feel better.

- Things to be careful of

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

Driving and using machines

Asketon rarely cause dizziness. Don't drive or use machines if you do not feel well.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate and often disappear after a short time.

- Uncommon: A reduction in white blood cells
- Not known: Low blood platelet
- Not known: allergic reaction
- Uncommon: elevated prolactin level
- Not known: enlargement of breast in male
- Uncommon: diarrhoea, constipation, abdominal pain, excessive saliva flow
- Not known: feeling not well
- Uncommon: blood urea nitrogen and creatinine increase
- Not known: jaundice
- Rare: rash, redness and severe itching of skin
- Uncommon: chest or back pain
- Uncommon: fatigue
- Uncommon: easily irritated

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You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)]

Storage and Disposal of Asketon

- Storage

Keep this medicine out of sight and reach of children.

Store below 30°C in the original package.

- Disposal

Do not use this medicine after the expiry date stated on the carton and blister after “EXP”.

Avoid release in environment.

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.

Product description

- What it looks like

Asketon 50mg is a white, round, biconvex, film-coated tablet with diameter 7mm.

Asketon film-coated tablets are available in pack size of 30's and 100's, packed in carton boxes with clear PVC/PVDC-Alu blisters strips.

- Ingredients

- Active ingredient

The active substance is itopride hydrochloride.

- Inactive ingredients

The other ingredients are:

Tablet core: Lactose monohydrate, Carmellose, Starch, pregelatinised, Silica, colloidal anhydrous, Magnesium Stearate.

Film-coating: Hypromellose 2910, Titanium Dioxide E171, Macrogol 6000, Talc.

- MAL number:

MAL23056023AZ

Product registration holder

Komedic Sdn Bhd,
4 Jalan PJS 11/14, Bandar Sunway,
46150 Petaling Jaya, Selangor D.E.

Date of revision

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Manufacturer

Medochemie Ltd (Central Factory),
1-10, Constantinoupoloes Str., 3011,
Limassol, Cyprus