

FEXUCLUE 40MG FILM-COATED TABLETS

Fexuprazan hydrochloride 40mg is equivalent to 36.74 mg Fexuprazan free base

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What FEXUCLUE is used for

FEXUCLUE is used for the treatment of gastric-acid related diseases including erosive esophagitis (EE) in adults.

How FEXUCLUE works

Fexuprazan Hydrochloride has a mechanism of action to inhibit gastric acid secretion by controlling H⁺/K⁺ -ATPase in parietal cells of stomach in a K⁺ ion-dependent and reversible manner. It directly inhibits the proton pump without undergoing acid-induced activity.

Before you use FEXUCLUE

- When you must not use it

Do not take this medicine if:

- you have hepatic impairment (no experience of use)
- you have renal impairment (no experience of use)
- you are elderly
- you have a history of hypersensitivity to the product or its components
- you are taking a drug containing atazanavir, nelfinavir, or rilpivirine
- you are pregnant and breastfeeding
- you have congenital conditions for lactose such as galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, as this medicine contains lactose.

- Before you start to use it

Consult with your doctor before taking FEXUCLUE

FEXUCLUE contains TARTRAZINE. This is a colouring agent, which may cause allergic reactions.

- Taking other medicines

Do not take this medicine if you are taking a drug containing atazanavir, nelfinavir, or rilpivirine

How to use FEXUCLUE

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Take 1 tablet once a day

- When to use it

This drug can be taken with or without meals

- How long to use it

You need to take the tablet orally once a day for 4 to 8 weeks. In cases where mucosal breaks have not healed within 4 weeks, an additional 4-week treatment may be considered.

- If you forget to use it

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

- If you use too much (overdose)

No cases of severe overdose of this drug have been reported. In clinical trials, there has been experience of single dose of the Product up to 320 mg. In the event of overdose, the patient should be monitored for symptoms of toxicity and if necessary, general adjuvant treatment should be provided.

While you are using FEXUCLUE

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using FEXUCLUE.

Tell your doctor immediately if you become pregnant while using this medication.

Take FEXUCLUE only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give FEXUCLUE to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how FEXUCLUE affects you.

Side effects

As with other drugs, this drug may cause side effects, even though not everyone gets them.

- Possible side effects are

Gastrointestinal disorders:

- Dyspepsia, diarrhea, nausea, abdominal discomfort, chronic gastritis, gastritis, erosive gastritis
- Skin and subcutaneous tissue disorders:

- Erythema

Nervous system disorders:

- Headache

Musculoskeletal and connective tissue disorders:

- Back pain

- Other possible side effects that may rarely occur:

Gastrointestinal disorders:

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- Hiatal hernia, Brunner's gland hyperplasia

Infections and infestations:

- Bronchitis, herpes simplex, influenza, periodontitis, pharyngitis, vaginal infections

Skin and subcutaneous tissue disorders:

- Dermatitis contact, pruritus, swelling face

General disorders and

administration site conditions:

- Chest discomfort, feeling abnormal, edema, pain, fever

Nervous system disorders:

- Dizziness, taste disturbance / altered taste

Musculoskeletal and connective tissue disorders:

- Muscle pain, musculoskeletal pain, neck pain

Eye disorders:

- Cataract, conjunctival haemorrhage, retinal tear

Ear and labyrinth disorders:

- Ear discomfort

Respiratory, thoracic and mediastinal disorders:

- Runny nose

Metabolic and nutritional disorders:

- Hypertriglyceridemia

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of FEXUCLUE

- Storage

Store at temperatures not exceeding 30°C.

Keep out of reach of children

Be aware that changing it to

another container may cause an accident or is not desirable in terms of quality maintenance.

- Disposal

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

Product Description

- What it looks like

Pale-green, Oblong film-coated tablet

- Ingredients

- Active ingredient

- Fexuprazan hydrochloride
- Inactive ingredients
- 40 mg Fexuprazan hydrochloride is equivalent to 36.74 mg Fexuprazan free base

- Lactose monohydrate

- Microcrystalline cellulose

- Croscarmellose sodium

- Magnesium stearate

- Ferric oxide yellow,

- Opadry white 03B28796

- Opadry green AMB2 88A610038

MAL number

Manufacturer

Daewoong Pharmaceutical Co., Ltd.

1, Osongsaengmyeong 2-ro, Cheongju-si, Chungcheongbuk-do, Republic of Korea

Product Registration Holder

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