SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fexuclue 40 mg Film-coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film-coated tablet contains 40 mg Fexuprazan as hydrochloride

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pale green, oblong, film-coated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fexuclue is for the treatment of erosive esophagitis (EE).

4.2 Posology and method of administration

Posology

Fexuclue is administered to adults as follows.
Treatment of erosive esophagitis (EE)
- 40 mg is administered orally once a day for 4 weeks.
- In the case of patients with untreated esophagitis or symptoms persisting, the administration given for another 4 weeks.

Method of administration

Fexuclue can be administered with or without meals.

4.3 Contraindications

1) Patients who have a history of hypersensitivity to Fexuclue or its components
2) Patients taking a drug containing atazanavir, nelfinavir, or rilpivirine (see section 4.5. Interactions)
3) Pregnant and lactating women (see section 4.6. Fertility, pregnancy, and lactation')
4) Patients who have congenital conditions for lactose such as galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, as this medicine contains lactose

4.4 Special warnings and precautions for use

The following patients should be administered with care
1) Patients with hepatic impairment (no experience of use)
2) Patients with renal impairment (no experience of use)
3) Elderly

4) Patients who have a history of hypersensitivity or allergy to Tartrazine aluminum lake (FD&C Yellow No. 5)

Pediatric Use
The clinical safety and efficacy of Fexuprazan HCl in children and adolescents have not been established.

Geriatric Use
In general, physiological functions such as hepatic functions or renal functions are deteriorated in the elderly, so it should be administered carefully.

Use in Patients with Renal Impairment
The safety and efficacy of Fexuprazan HCl in patients with renal impairment have not been established.

Use in Patients with Hepatic Impairment
The safety and efficacy of Fexuprazan HCl in patients with hepatic impairment have not been established.

General Cautions
1) Since Fexuprazan HCl may relieve symptoms of malignant tumors or delay the diagnosis, if a malignant tumor is suspected by warning symptoms (unintended significant weight loss, recurrent vomiting, dysphagia, hemoptysis, melena, etc.) and a gastric ulcer is present or suspected, it should be administered after confirming that it is not malignant.

2) The number of bacteria usually present in the gastrointestinal tract increases when acidity in the stomach decreases due to proton pump inhibitors (PPIs). The risk of infection of the gastrointestinal tract by bacteria such as Salmonella, Campylobacter and Clostridium difficile may slightly increase when treated with gastric acid inhibitors. This is associated with an increased risk of Clostridium difficile diarrhea and several observational studies have reported that this risk is increased, especially in hospitalized patients. This diagnosis should be considered when diarrhea does not improve. Clostridium difficile diarrhea has been reported with the used of almost all antimicrobial agents.

3) Proton Pump Inhibitor (PPI) treatment has been reported to have the potential of being associated with an increased risk of osteoporosis-related fractures of the hip, wrist and spine. The risk of fracture was increased in patients receiving high doses of PPIs (defined as repeated daily administration) and in patients with long-term use longer than a year. In the case of patients at risk of developing osteoporosis and osteoporotic fractures, appropriate clinical monitoring is recommended according to the latest clinical guidelines.

4) Hypomagnesemia was rarely reported in patients who had been under treatment with a proton pump inhibitor (PPI) for more than 3 months and the most frequent cases were treated for more than a year. In most patients, treatment of hypomagnesemia requires magnesium supplementation and discontinuation of PPI. Patents requiring long-term treatment or co-administering digoxin or drugs that cause hypomagnesemia (e.g., diuretics) require periodic monitoring of magnesium levels, including at the initiation of treatment. Serious adverse events include stiffness, arrhythmia and seizures.

4.5 Interaction with other medicinal products and other forms of interaction

1) Since the administration of Fexuprazan HCl raises the pH in the stomach, it can interact with drug absorption in the case of oral drugs, where the pH of the stomach is an important determinant

of bioavailability. Therefore, the use of Fexuprazan HCl may reduce the bioavailability of drugs that depends on the gastric pH, such as atazanavir and nelfinavir.

2) Fexuprazan HCl is mainly metabolized by CYP3A4 and partially by CYP2B6, CYP2C19 and CYP2D6.

3) When 80 mg of Fexuprazan HCl and clarithromycin were co-administered, the AUCτ of Fexuprazan HCl and clarithromycin were shown to be 1.1 times and 0.77 times, respectively, which were not clinically significant.

4) When Fexuprazan HCl, clarithromycin and amoxicillin were co-administered, the AUCτ of amoxicillin was shown to be 0.86 times, but it was not clinically significant.

4.6 Fertility, pregnancy, and lactation

1) Pregnant women
There are no clinical trial data of Fexuprazan HCl in pregnant and lactating women. As a result of embryo-fetal development tests in rats and rabbits, maternal body weight and feed intake decreased, but there was no effect on embryo-fetal development. For safety reasons, the use of Fexuprazan HCl during pregnancy is prohibited.

2) Lactating women
Breastfeeding should be discontinued if Fexuprazan HCl is used as it is not known if Fexuprazan HCl will pass to breast milk in lactating women. In animal studies (rats), it has been reported that Fexuprazan HCl passes into breast milk.

4.7 Effects on ability to drive and use machines

Not relevant. If you experience dizziness and visual disturbances after taking Fexuclue, you should not drive or use machines.

4.8 Undesirable effects

a. Summary of the safety profile
A total of two clinical trials were conducted in patients with erosive esophagitis (EE). Of the subjects who participated in the clinical trials, 183 subjects received 40 mg of Fexuprazan HCl. Among them, 12 subjects (6.56 %) experienced 19 cases of adverse drug reactions. The most frequent adverse drug reaction was diarrhoea (3 subjects, 1.64 %, 3 cases), followed by abdominal discomfort, dyspepsia and headache, pruritus (2 subjects, 1.09 %, 2 cases, respectively).

b. Tabulated summary of adverse drug reactions
The following adverse drug reactions have been identified in the clinical trials in patients with erosive esophagitis (EE). The adverse drug reactions are presented according to the system organ class (SOC) and the preferred term (PT) of MedDRA. Common and uncommon adverse drug reactions (marked with *) reported in clinical trials are as follows. Frequency categories are defined according to the following convention: Common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100).

Table 1. Adverse reactions reported in patients with erosive esophagitis (EE) from the 2 clinical trials.

System Organ Class	Preferred Term (PT)	
	Common	**Uncommon**
Gastrointestinal disorders	Diarrhea*, abdominal discomfort*, dyspepsia*, nausea*, chronic gastritis, gastritis, gastritis erosive	Hiatus hernia, Brunner's gland hyperplasia
Nervous system disorders	Headache*	Dysgeusia*, dizziness
Skin and subcutaneous tissue disorders	Erythema*, pruritus*	Swelling face*, dermatitis contact
Musculoskeletal and connective tissue disorder	Back pain	Myalgia*, musculoskeletal pain, neck pain
General disorders and administration site conditions		Feeling abnormal*, edema, pyrexia, chest discomfort, pain
Ear and labyrinth disorders		Ear discomfort*
Eye disorders		Conjunctival haemorrhage*, cataract, retinal tear
Infections and infestations		Influenza, herpes simplex, pharyngitis, bronchitis, periodontitis, vaginal infection
Respiratory, thoracic and mediastinal disorders		Rhinorrhoea
Metabolism and nutrition disorders		Hypertriglyceridemia

* Note: This frequency is based on the results from only clinical trials, and the number of subjects analyzed is small.

c. Description of selected adverse reactions

In two clinical trials conducted in patients with erosive esophagitis (EE), there were no serious adverse drug reactions for Fexuclue.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560 Email: pv-center@pom.go.id Website: https://e-meso.pom.go.id/ADR	PT Daewoong Pharmaceutical Indonesia WeWork Revenue Tower 20th Floor SCBD, Lot 13 District 8, Jl. Jenderal Sudirman Kav. 52-53 RT. 5 RW.3, Senayan, 12190 24-hour Pharmacovigilance Unit Phone: +62 889-7580-0212 Email: safety_dwi@daewoong.co.kr Website: https://daewoongpharm.id/

4.9 Overdose

No cases of severe overdose of Fexuprazan HCl have been reported. In clinical trials, there has been experience of single dose of Fexuprazan HCl 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code
A02BC10

Pharmacological actions
Fexuprazan HCl 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. Fexuprazan HCl directly inhibits the proton pump without undergoing acid-induced activity.

1) Clinical studies
(1) Erosive esophagitis
A randomized, double-blind, comparative phase 3 clinical trial with 40 mg of Fexuprazan HCl or 40 mg of Esomeprazole administered orally once daily for up to 8 weeks was conducted in 218 patients with erosive esophagitis. As a study result, the cumulative healing rate at Week 8 is shown in the table below and the non-inferiority of Fexuprazan HCl to esomeprazole group was confirmed (Table 2).

Table 2. Cumulative healing rate at Week 8 in patients with erosive esophagitis (PPS; Per Protocol Set)**

	Fexuprazan HCl 40 mg (N=107)	Esomeprazole 40 mg (N=111)
Cumulative Healing Rate n (%)	106 (99.07)	110 (99.10)
	0.89[a] [−0.86, 2.64][b] 0.3378[c]	

a) Healing rate difference, % (baseline LA grade correction, Cochran Mantel-Haenszel Method)
b) 95% confidence interval of healing rate difference,
c) p-value
* Non-inferiority margin: -10%
** Study number: DW_DWP14012301

5.2 Pharmacokinetic properties

1) Absorption
When single administration of 10~320 mg of Fexuprazan HCl carried out in healthy adults, it was rapidly absorbed and the maximum plasma concentration reached at a median value of 1.75~3.5 hours after administration. Blood drug concentration increased as the dose increased. When 20~160 mg of Fexuprazan HCl was repeatedly administered orally for 7 days, the drug concentration in the steady state and terminal elimination half-life were similar to that of the single administration. There was no accumulation of *in vivo* exposure after repeated administration and the drug concentration in blood tended to increase in proportion to the dose increase. As a result of orally administering 160 mg of Fexuprazan HCl to healthy adult males after fasting and high-fat diet to evaluate the

dietary effect on bioavailability, there were no significant differences in *in vivo* exposure and pharmacodynamic endpoints (retention time above pH 4 in the stomach).

2) Distribution
The *in vitro* plasma protein binding rates in human plasma were 94.3% and 92.8% at concentrations of 1 and 10 μg/mL, respectively.

3) Metabolism
Fexuprazan HCl is mainly metabolized by CYP3A4, the main metabolite is metabolite M14 and this metabolite is ineffective.

4) Excretion
The amounts of unchanged forms excreted from urine and feces after intravenous administration in rats were 0.61% and 34.22%. After oral administration of the ^{14}C marker of Fexuprazan HCl to rats, the excretion recovery rate at 120 hours was 98.9%, where the recovery rates of urine and feces were 18.8% and 80.1%, respectively.
After single oral administration to biliary tract intubated rats, the bile was excreted at 88.0% at 48 hours and the total recovery rate was 98.2%. After oral administration of the ^{14}C marker of Fexuprazan HCl to dogs, the fecal recovery rate at 168 hours was 96.7%, where the recovery rates of urine and feces were 38.8% and 57.9%, respectively.
After oral administration of Fexuprazan HCl to healthy adult males, the mean elimination half-life of unchanged forms and metabolite M14 were 9.7 hours and 14.2 hours, respectively. The urine excretions and elimination rate of the unchanged form were about 0.6% and 0.63 L/hr, respectively.

5) Drug -Drug Interaction
(1) Drugs that may affect the plasma concentration of Fexuprazan HCl

① Fexuprazan HCl is a substrate of CYP3A4 and when Fexuprazan HCl and a CYP3A4 inhibitor were administered in combination, the increase in exposure of Fexuprazan HCl may be slight.
The AUC_T of Fexuprazan HCl increased slightly to 1.1 times as a result of co-administration of 80 mg of Fexuprazan HCl and 500 mg as clarithromycin twice a day for 7 days in healthy adult males.

(2) Drugs whose plasma concentration may be changed by Fexuprazan HCl

① Fexuprazan HCl showed competitive inhibitory effect against CYP3A4 in *in vitro*, but its IC50 (11.7 μM) was about 100 times higher than the maximum plasma concentration in the clinical dose (40 mg basis).

② As a result of co-administration of three preparations, 80 mg of Fexuprazan HCl, 1 g as amoxicillin and 500 mg as clarithromycin twice a day for 7 days to healthy adult males, the AUC_T and Css,max of clarithromycin were decreased to 23% and 27%, respectively and the AUC_T and Css,max of amoxicillin were decreased to 14% and 33%, respectively.

③ Fexuprazan HCl showed competitive inhibitory effect against MATE1, MATE2K and OCT1 in *in vitro*, but it is unlikely to increase the blood concentration of the transporter substrate drug when considering the maximum plasma concentration at the clinical dose (40 mg basis).

5.3 Preclinical safety data

Genotoxicity
Fexuprazan HCl was negative in all of the bacterial reverse mutation tests using *Salmonella* and *E. coli*, chromosomal abnormality tests using CHO cell lines and micronucleus tests using rats.

Reproductive and Developmental Toxicity
As a result of fertility and early embryo development tests in rats, there was no effect on fertility and early embryo development up to a dose of 50 mg/kg/day. As a result of the embryo-fetal

development test in rats, a decrease in feed intake and weight was observed in the group administered with more than 30 mg/kg/day. The weight of the fetus decreased by 5%, but there was no effect on development or growth delay. The no-effect levels (NOELs) of embryo-fetal and the maternal were confirmed to be 60 mg/kg/day (about 19.8 times the clinical dose of 40 mg AUC) and 15 mg/kg/day (7.5 times the clinical dose 40 mg AUC), respectively. As a result of the embryo-fetal development test in rabbits, a decrease in feed intake and weight and constipation symptoms were observed in the group administered with more than 15 mg/kg/day. However, there was no effect on development or growth delay. The no-effect levels (NOELs) of the maternal and embryo-fetal were confirmed to be 10 mg/kg/day (0.6 times the clinical dose of 40 mg AUC) and 15 mg/kg/day (1.7 times the clinical dose 40 mg AUC), respectively. As a result of prenatal development and maternal function evaluation tests in rats, there was no effect on the offspring immediately after childbirth by Fexuprazan HCl, but it was transferred to maternal milk and the body weight decreased during the breastfeeding period in the administration dose of more than 7.5 mg/kg/day (3.7 times the clinical dose 40 mg AUC). However, no dysfunctions including behavior, development, sexual maturity and genital organs of the offspring even at the high dose of 30 mg/kg/day (17.2 times the clinical dose 40 mg AUC).

Carcinogenicity
In a carcinogenicity study administered orally in rats for 2 years, gastric neuroendocrine tumors were observed at 10mg/kg/day (about 3.7 times based on the clinical dose 40mg/day AUC) for males and 5mg/kg/day (about 4.1 times based on the clinical dose 40mg/day AUC) for females. In the 26-week carcinogenicity test in RasH2 mice, gastric benign adenomas were observed at 60mg/kg/day in males (about 26.9 times based on the clinical dose 40mg/day AUC).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Lactose monohydrate
Microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate
Ferric oxide yellow

Film Coating
Opadry white 03B28796 (Film coating 1):
- Hypromellose 2910
- Titanium dioxide
- Polyethylene glycol 400

Opadry AMB2 Green 88A610038 (Film coating 2):
- Polyvinyl alcohol
- Talc
- Titanium dioxide
- Glycerol esters of fatty acids
- Sodium lauryl sulfate
- Tartrazine aluminum lake (FD&C Yellow No. 5)
- Brilliant blue FCF aluminum lake

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30ºC in an airtight container.
Precautions for Storage and Handling
1) Keep out of reach of children.
2) Be aware that changing it to another container may cause an accident or is not desirable in terms of quality maintenance.

6.5 Nature and contents of container

The tablets are packaged in soft aluminum foil (PVC/AL/NY) and hard aluminum foil (AL+HSL+VMCH Coating) blisters. Each blister packaging unit has 7 tablets per PTP plate.

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. NAME AND ADDRESS OF MANUFACTURER

Daewoong Pharmaceutical Co., Ltd.
Cheongju-si, Republic of Korea

8. MARKETING AUTHORISATION HOLDER

PT Daewoong Pharmaceutical Indonesia, Cikarang, Indonesia
Phone: +62 21 3972 1100, Website: https://daewoongpharm.id/

9. MARKETING AUTHORISATION NUMBER(S)

FEXUCLUE, 40mg Film-coated Tablet, Box of 4 blisters @ 7 film-coated tablets,
Reg. No. DKI XXXXXXXX

10. DATE OF FIRST AUTHORISATION

11. DATE OF REVISION OF THE TEXT

HARUS DENGAN RESEP DOKTER

INFORMASI PRODUK UNTUK PASIEN

FEXUCLUE
Fexuprazan HCl 40 mg
Tablet salut selaput

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini berisi hal-hal penting untuk Anda

- Simpanlah leaflet ini. Anda mungkin perlu membacanya di kemudian hari
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakanlah dokter atau apoteker Anda
- Obat ini telah diresepkan khusus untuk Anda. Dilarang memberikan obat ini untuk orang lain karena hal ini dapat membahayakan mereka, meskipun tanda dan gejala penyakit mereka sama dengan yang Anda alami.
- Apabila Anda mengalami efek samping, komunikasikanlah pada dokter atau apoteker Anda. Perhatikan pula kemungkinan efek samping yang tidak terdaftar dalam leaflet ini.

Informasi yang terkandung dalam leaflet ini :

1. Nama Produk
FEXUCLUE

2. Bentuk Sediaan
Tablet Salut Selaput

3. Deskripsi Produk
Hijau pucat, tablet salut selaput berbentuk lonjong.

4. Apa saja yang terkandung dalam produk ini?
Bahan aktif dalam obat ini adalah Fexuprazan. Setiap tablet mengandung Fexuprazan HCl 40 mg

5. **Kekuatan**
   Tiap tablet salut selaput mengandung Fexuprazan HCl 40 mg

6. **Untuk apa produk ini digunakan?**
   FEXUCLUE memiliki kandungan bahan aktif Fexuprazan HCl. Setiap tablet salut selaput mengandung obat ini yang bekerja dengan menghambat produksi asam lambung dengan mengendalikan enzim H^+/K^+-ATPase pada sel parietal. Obat ini menghambat pompa proton secara langsung dan bekerja secara reversibel.

   FEXUCLUE mempunyai indikasi untuk pengobatan esofagitis erosif.

7. **Seberapa banyak dan seberapa sering Anda harus menggunakan obat ini ? Apa yang harus Anda lakukan jika Anda lupa minum satu dosis?**
   FEXUCLUE diberikan pada pasien dewasa dengan dosis 40 mg secara oral sekali sehari selama 4 minggu. Pada pasien dengan esofagitis yang belum sembuh atau dengan gejala yang masih menetap, terapi dapat dilanjutkan hingga 4 minggu berikutnya. Obat ini dapat diminum dengan atau tanpa makanan.

8. **Kapan Anda tidak boleh menggunakan produk ini?**
   Jangan menggunakan FEXUCLUE, jika :
   - Anda memiliki riwayat hipersensitivitas atau alergi terhadap produk ini atau bahan – bahan lain yang terkandung dalam obat ini.
   - Anda sedang menggunakan obat yang mengandung atazanavir, nelfinavir atau rilpivirine
   - Anda sedang hamil dan menyusui
   - Anda memiliki kondisi bawaan seperti intoleransi galaktosa, defisiensi Lapp lactase atau malabsorpsi glukosa-galaktosa karena obat ini mengandung laktosa.

9. **Apa yang harus diperhatikan saat Anda menggunakan produk ini?**
   Konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan FEXUCLUE, jika:
   - Anda mengalami gangguan fungsi hati (belum ada pengalaman penggunaan obat ini)
   - Anda mengalami gangguan fungsi ginjal (belum ada pengalaman penggunaan obat ini)
   - Anda berusia lanjut (lansia)
   - Anda memiliki riwayat hipersensitivitas atau alergi terhadap tartrazine aluminum lake (FD&C Yellow No.5)

   Peringatan lain terkait penggunaan obat ini:

   - Jika Anda mengalami gejala seperti penurunan berat badan yang tidak disengaja, muntah berulang, kesulitan menelan, batuk berdarah, atau tinja berwarna hitam, serta memiliki atau dicurigai memiliki tukak lambung, segera konsultasikan dengan dokter sebelum menggunakan obat ini. Dokter akan menilai kondisi Anda untuk menentukan pengobatan yang sesuai.
   - Jika Anda mengalami diare yang tidak membaik atau berlangsung lama selama menggunakan obat ini, segera konsultasikan dengan dokter untuk mendapatkan penanganan yang tepat.
   - Jika Anda memiliki risiko osteoporosis, konsultasikan dengan dokter sebelum menggunakan obat ini, terutama jika digunakan dalam dosis tinggi atau dalam jangka waktu lama. Dokter mungkin akan menyarankan pemantauan kesehatan secara berkala.
   - Penggunaan obat yang menurunkan asam lambung dalam jangka waktu lama dapat menyebabkan kadar magnesium dalam darah menjadi rendah (hipomagnesemia). Jika

Anda menggunakan obat ini dalam waktu lama atau juga menggunakan obat lain seperti digoksin atau obat diuretik, dokter mungkin akan melakukan pemeriksaan kadar magnesium secara berkala. Jika diperlukan, dokter dapat menganjurkan pemberian suplemen magnesium atau penyesuaian pengobatan.
Segera konsultasikan dengan dokter jika Anda mengalami gejala seperti kejang otot, detak jantung tidak teratur, atau kejang.

10. Apa saja obat atau makanan lain yang harus diperhatikan selama penggunaan obat ini?

Beri tahu dokter atau apoteker jika Anda sedang menggunakan obat lain, karena FEXUCLUE dapat mempengaruhi atau dipengaruhi oleh obat-obatan tertentu.
Beberapa obat yang perlu diperhatikan antara lain:

- Atazanavir, Nelfinavir
- Clarithromycin
- Penggunaan bersamaan Clarithromycin dan Amoxicillin

Jika Anda sedang menggunakan obat-obatan tersebut atau obat lain, konsultasikan dengan dokter atau apoteker sebelum menggunakan FEXUCLUE.

11. Kehamilan dan Menyusui

FEXUCLUE tidak dianjurkan digunakan selama kehamilan atau jika Anda sedang merencanakan kehamilan.
Jika Anda sedang menyusui, konsultasikan dengan dokter sebelum menggunakan obat ini. Dokter mungkin akan menyarankan untuk menghentikan menyusui atau menghentikan penggunaan obat, sesuai dengan kondisi Anda.

12. Berkendara dan menggunakan mesin

Jika Anda mengalami pusing atau gangguan keseimbangan setelah menggunakan FEXUCLUE, Anda tidak dianjurkan untuk mengemudi atau mengoperasikan mesin

13. Apa saja efek samping yang mungkin terjadi akibat penggunaan produk ini?

Efek samping yang mungkin terjadi:
Seperti obat lainnya, FEXUCLUE dapat menimbulkan efek samping, walaupun tidak semua orang mengalaminya.
Efek samping yang umum:

- Diare, rasa tidak nyaman pada perut, gangguan pencernaan, mual, radang lambung (gastritis) termasuk gastritis kronis, gastritis erosif
- Sakit kepala
- Kemerahan pada kulit, gatal
- Nyeri punggung

Efek samping lain yang tidak umum terjadi:

- Hernia hiatus, pembesaran kelenjar Brunner
- Perubahan rasa pada lidah, pusing
- Pembengkakan pada wajah, dermatitis kontak (radang kulit akibat kontak)
- Nyeri otot, nyeri pada sistem otot dan tulang, nyeri leher
- Perasaan tidak normal, pembengkakan (edema), demam (pyrexia), ketidaknyamanan di dada, nyeri
- Ketidaknyamanan pada telinga
- Perdarahan pada konjungtiva (bagian putih mata), katarak, mata berair
- Influenza, herpes simpleks, radang tenggorokan (faringitis), bronkitis, radang jaringan penyangga gigi (periodontitis), infeksi vagina
- Pilek (rinore)
- Peningkatan kadar trigliserida dalam darah

Pada penelitian klinis yang dilakukan pada pasien dengan esofagitis erosif, tidak ditemukan efek samping serius yang berhubungan dengan penggunaan FEXUCLUE.

Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau kondisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak berikut:

PT Daewoong Pharmaceutical Indonesia
WeWork Revenue Tower 20th Floor SCBD, Lot 13 District 8, Jl. Jenderal Sudirman Kav. 52 53 RT. 5 RW.3, Senayan, 12190

24-hour Pharmacovigilance Unit
Phone: +62 889-7580-0212
Email: safety_dwi@daewoong.co.kr
Website: https://daewoongpharm.id/

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

14. Apa yang harus saya lakukan jika saya mengonsumsi lebih dari dosis yang dianjurkan?

Belum ada laporan kasus overdosis berat dari Fexuprazan HCl. Dalam uji klinis, penggunaan dosis tunggal hingga 320 mg Fexuprazan HCl telah pernah dilaporkan.
Jika terjadi overdosis, pasien harus dipantau terhadap kemungkinan munculnya gejala keracunan. Bila diperlukan, pengobatan suportif atau penanganan umum yang sesuai dapat diberikan.
Jika Anda khawatir telah mengonsumsi obat ini melebihi dosis yang dianjurkan, segera hubungi dokter atau tenaga kesehatan.

15. Bagaimana cara menyimpan obat ini?

Simpan pada suhu dibawah 30°C dalam wadah kedap udara. Jauhkan dari jangkauan anak – anak

16. Bahan tambahan obat

FEXUCLUE tablet salut selaput mengandung bahan tambahan *lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, ferric oxide yellow, opadry white 03B28796 (*mengandung *hypromellose 2910, titanium dioxide, polyethylene glycol 400), opadry AMB2 Green 88A610038 (*mengandung *polyvinyl alcohol, talc, titanium dioxide, glycerol esters of fatty acids, sodium lauryl sulfate, tartrazine aluminum lake (FD&C Yellow No.5), brilliant blue FCF aluminum lake)*

17. Nomor izin edar (NIE)

FEXUCLUE 40 mg Tablet Salut Selaput
Dus, 4 blister @ 7 Tablet Salut Selaput
No. Reg. :

18. Nama dan Alamat produsen dan pemegang izin edar

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19. Tanggal revisi leaflet pasien

08 April 2026

HARUS DENGAN RESEP DOKTER