SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Feksine 180 mg Film Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Fexofenadine HCl

Excipients:

For excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet
White, film coated, oblong tablet.

4. CLINICAL PROPERTIES

4.1 Therapeutic Indications

It is indicated for the relief of symptoms of chronic idiopathic urticaria such as skin itching and redness in adults and children aged 12 years and over.

4.2 Posology and Method of Administration

Posology/Administration frequency and duration:

The recommended dose of fexofenadine hydrochloride for adults and children 12 years of age and older is 180 mg once daily.

Method of administration:

Feksine is used orally.

Administration of an antacid containing aluminum and magnesium hydroxide gel 15 minutes prior to Feksine resulted in a decrease in bioavailability, most likely due to binding in the gastrointestinal tract. For this reason, it is recommended to leave a 2-hour interval between the administration of Feksine and the administration of antacids containing aluminum and magnesium hydroxide.

Additional information about special populations:

Renal/Liver failure:

There are limited studies covering special risk groups (elderly, patients with kidney or liver disorders). Therefore, Feksine should be used with caution in special risk groups.

Pediatric population:

The efficacy and safety of fexofenadine hydrochloride have not been studied in children under 12 years of age.

Geriatric population:

There are limited studies covering special risk groups (elderly, patients with kidney or liver disorders). Therefore, Feksine should be used with caution in special risk groups.

4.3 Contraindications

It is contraindicated in patients known to be hypersensitive to any of the components of Feksine.

4.4 Special warnings and special precautions for use

Feksine should be used very carefully in the elderly, patients with renal or hepatic impairment.

Patients with a history of cardiovascular disease or ongoing cardiovascular disease should be warned about the side effects of antihistamine drugs such as tachycardia and palpitations.

4.5 Interaction with other medicinal products and other forms of interaction

Fexofenadine does not undergo hepatic biotransformation and therefore does not interact with other drugs through its hepatic mechanisms. Co-administration of fexofenadine hydrochloride with erythromycin or ketoconazole resulted in a 2-3-fold increase in fexofenadine plasma levels. These changes were not accompanied by any effect on the QT interval and there was no increase in adverse events compared to drugs given alone.

Animal studies have shown that the increase in plasma levels of fexofenadine after co-administration with erythromycin or ketoconazole may be due to an increase in gastrointestinal absorption and a decrease in biliary excretion or gastrointestinal secretion.

No interaction was observed with fexofenadine and omeprazole. However, administration of an antacid containing aluminum and magnesium hydroxide gel 15 minutes prior to fexofenadine hydrochloride resulted in a decrease in bioavailability, most likely due to binding in the gastrointestinal tract. Therefore, a 2 hour interval is recommended between administration of fexofenadine hydrochloride and administration of antacids containing aluminum and magnesium hydroxide.

Fexofenadine can increase the effect of ethyl alcohol, anticholinergics and central nervous system depressants.

Fexofenadine may reduce the effect of acetylcholinesterase inhibitors (central) and betahistine.

The effect of fexofenadine may be reduced by acetylcholinesterase inhibitors (central), amphetamines, grapefruit juice, p-glycoprotein inducers and rifampin.

Fexofenadine levels may decrease in the presence of St. John's wort.

4.6 Pregnancy and lactation

General advise

Pregnancy category: C

Women of childbearing potential/Contraception

There are no sufficient data from the use of fexofenadine hydrochloride in women of childbearing potential. Therefore, it is not recommended to become pregnant during the use of the drug.

Pregnancy

There are no sufficient data from the use of fexofenadine hydrochloride in pregnant women. As with other drugs, fexofenadine hydrochloride should not be used during pregnancy unless the expected benefits to the patient outweigh the potential risk to the foetus.

Lactation

There are no data on whether fexofenadine hydrochloride passes into breast milk. However, fexofenadine has been found to be excreted in human milk when terfenadine is administered to lactating mothers. Therefore, fexofenadine hydrochloride is not recommended for lactating mothers.

Reproduction ability/Fertility

Extensive reproductive toxicity studies in mice have shown that fexofenadine does not impair fertility, is not teratogenic, and does not adversely affect prenatal and postnatal development.

4.7 Effects on ability to drive and use machines

Based on the pharmacodynamic profile and reported adverse events, fexofenadine hydrochloride tablets are unlikely to have an effect on the ability to drive and use machines. Objective tests have shown that Feksine has no significant effect on central nervous system function. This means that patients can drive or do work that requires concentration.

4.8 Undesirable effects

Adverse effects in placebo-controlled clinical trials were compared in patients treated with placebo and patients treated with fexofenadine.

Undesirable effects listed below are classified according to frequency groupings through the following convention.

Very common (≥1/10); common (between ≥1/100 and <1/10); uncommon (between ≥1/1000 and <1/100); rare (between ≥1/10.000, and <1/1000); very rare (<1/10.000), not known (cannot be estimated with the available data).

Immune system diseases:

Rare: Redness, urticaria, pruritus and angioedema, chest tightness, dyspnea, hypersensitivity reactions with symptoms such as burning sensation and systemic anaphylaxis.

Nervous system diseases:

Very common: Headache (3%), drowsiness (1-3%), dizziness (1-3%)

Common: insomnia, nervousness, sleep disturbances or paronychia

Cardiac diseases:

Not known: tachycardia, palpitation

Gastrointestinal diseases:

Very common: Nausea (1-3%)

Not known: Diarrhea

Skin and subcutaneous tissue diseases:

Not known: redness, pruritus, urticaria

Musculoskeletal diseases:

Very common: Myalgia (3%)

General disorders and diseases:

Uncommon: Fatigue

4.9 Overdose

Most reports of fexofenadine hydrochloride overdose have limited data. However, fatigue, dizziness and dry mouth have been reported. Studies in healthy volunteers at doses up to 800 mg once daily and up to 690 mg twice daily for one month or 240 mg daily for 1 year did not show any clinically significant adverse effects compared to placebo. The maximum tolerated dose of Feksine has not been determined. Standard measures to remove any unabsorbed drug should be considered. Symptomatic and supportive treatment is recommended.

Hemodialysis does not effectively remove fexofenadine hydrochloride from the blood.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other systemic antihistamines

ATC Code: R05CB06

Fexofenadine is an antihistamine with selective peripheral H1-receptor antagonist activity. Fexofenadine inhibited sensitive bronchospasm in antigen-inducing guinea pigs and histamine release from peritoneal mast cells in rats. No anticholinergic or alpha-adrenergic-receptor blocking effects occurred in laboratory animals. In addition, no sedative or other central nervous system effects were observed. Distribution studies in radiolabeled tissue in mice indicate that fexofenadine does not cross the blood-brain barrier.

Fexofenadine hydrochloride inhibits the skin blisters and redness response induced by histamine injection. After a single dose and twice-daily oral administration, the antihistaminic effect occurs within one hour, the maximum effect is achieved within 2-3 hours and ends in a minimum of 12 hours. The maximum inhibition of the blistered and reddened area of the skin is greater than 80%. Tolerance to these effects did not develop in 28 days of use. Clinical studies of seasonal allergic rhinitis using the reflective total symptom score as the primary endpoint have shown that a dose of 120 mg/day is sufficient for effect.

5.2 Pharmacokinetic properties

Absorption:

Following oral ingestion, fexofenadine hydrochloride is readily absorbed by the body, reaching Tmax within 1-3 hours following the dose. The mean Cmax is approximately 142 ng/ml following a single dose of 60 mg, approximately 289 ng/ml following a single 120 mg dose, and approximately 494 ng/ml following a single 180 mg dose.

Distribution:

Fexofenadine is 60-70% connect to plasma proteins.

Biotransformation:

Fexofenadine gets change negligibly.

Elimination:

After a single dose of 60 mg oral fexofenadine, 80% of the total fexofenadine is excreted in the faeces and 11% in the urine. The terminal elimination half-life of fexofenadine is 11-16 hours following multiple dosing. While 10% of the ingested dose is excreted unchanged in the urine, elimination is thought to be mainly by the biliary route.

Linearity/non-linearity:

The pharmacokinetics of single and multiple doses of fexofenadine hydrochloride are linear from 20 mg to 120 mg. There was a proportional increase in the area under the curve (8.8%) after ingestion of 240 mg twice daily.

5.3 Preclinical safety data

Dogs tolerated a dose of 450 mg/kg twice daily for 6 months and showed no toxicity, except for rare vomiting. In addition, in single-dose dog and rodent studies, no visible dose-related findings were found at necropsy.

In tissue distribution studies in rats, radiolabeled fexofenadine hydrochloride showed that fexofenadine did not cross the blood brain barrier.

Fexofenadine hydrochloride was found to be non-mutagenic in various in vitro and in vivo mutagenicity studies.

The carcinogenic potential of fexofenadine hydrochloride has been evaluated using terfenadine studies in conjunction with supporting pharmacokinetic studies showing exposure to fexofenadine hydrochloride (via plasma AUC values). No evidence of carcinogenicity was observed in rats and mice given terfenadine (up to 150 mg/kg/day).

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Croscarmellose Sodium

Microcrystal Cellulose

Pregelatinized Corn Starch

Colloidal Anhydrous Silica

Povidone K-30

Magnessium Stearate

Lactose Monohydrate (obtained from cow's milk)

Hydroxypropyl Methyl Cellulose

Titanium Dioxide

Polyethyleneglycol 4000

6.2 Incompatibilities

There is no data.

6.3 Shelf Life

36 months.

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

Feksine film tablets are brought into use in white, opaque, PVC/PVDC aluminum foil blister packs..

6.6 Instructions for use and handling

Unused products or waste materials are disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORIZATION HOLDER

Drogsan İlaçlan San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. 7/3, 06520 Balgat-ANKARA

8. MARKETING AUTHORIZATION NUMBER

208/44 (in Turkey)

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization: 17.07.2006 (in Turkey)

Renewal of the authorization: 17.07.2011 (in Turkey)

10. DATE OF REVISION OF THE TEXT

04.10.2013