FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS

PL 04425/0667

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Aventis Pharma Limited, a Marketing Authorisation for the medicinal product, Fexofenadine hydrochloride 120 mg Film-Coated Tablets (PL 04425/0667), on 17 August 2011. The product is a prescription-only medicine (POM).

Fexofenadine hydrochloride 120 mg Film-Coated Tablets is an antiallergic medication. In adults and children aged 12 years and above fexofenadine hydrochloride is used to treat the symptoms of hayfever (allergic rhinitis), such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Fexofenadine hydrochloride 120 mg Film-Coated Tablets (PL 04425/0667) outweigh the risks; hence a Marketing Authorisation has been granted.
SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Aventis Pharma Limited, a Marketing Authorisation for the medicinal product, Fexofenadine hydrochloride 120 mg Tablets (PL 04425/0667), on 17 August 2011. The product is a prescription-only medicine (POM).

Fexofenadine hydrochloride 120 mg Film-Coated Tablets are for the symptomatic relief of hayfever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross referring to Telfast 120 mg Film-Coated Tablets (PL 04425/0157), authorised to Aventis Pharma Limited on 4 December 1996. The reference product has been authorised in the EEA for over 10 years.

No new data were submitted nor were they necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.
1. INTRODUCTION
This is a simple, informed consent application for Fexofenadine Hydrochloride 120 mg Film-Coated Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is Aventis Pharma Ltd, 50 Kings Hill, West Malling, Kent, ME19 4AH; trading as Sanofi- Aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

The application cross-refers to Telfast 120mg film coated tablets (PL 04425/0157) authorised to Aventis Pharma Limited on 4 December 1996. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name
The proposed name of the product is for Fexofenadine Hydrochloride 120 mg Film-Coated Tablets. The product has have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each film-coated tablet contains 120 mg of the active substance, fexofenadine hydrochloride, which is equivalent to 112 mg of fexofenadine.

The finished product is licensed for marketing in blister strips comprising of polyvinylchloride (PVC)/polyethylene (PE)/polyvinylidene chloride (PVdC) and aluminium foil. The blister strips are packaged with the Patient Information Leaflet (PIL) into cardboard outer cartons and are available in pack sizes of 2 (sample only), 7, 10, 15, 20, 30, 50, 100 and 200 ( as 10x20) tablets per package. Not all pack sizes may be marketed.

All primary product packaging complies with EU legislation regarding contact with food. The proposed shelf-life is 3 years. There are no special storage conditions for this medicinal product. The shelf-life and storage conditions are consistent with the details registered for the cross-reference product.

2.3 Legal status
This product is a prescription-only medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company
Aventis Pharma Ltd, 50 Kings Hill, West Malling, Kent, ME19 4AH, UK.

The Quality Person (QP) responsible for pharmacovigilance is stated and his curriculum vita has been provided.
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
The applicant has provided a declaration confirming that there are no materials of human or animal origin contained in or used in the manufacturing process for the proposed product. This is consistent with the cross-reference product.

3. EXPERT REPORTS
A satisfactory expert report and curriculum vita of the expert are provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The medicinal product is peach, modified capsule-shaped, film-coated tablet, debossed with ‘012’ on one side and a scripted ‘e’ on the other side. The appearance of the product is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The PIL is satisfactory and in line with the approved SmPC. It has been prepared according to the Quality Review of Documents (QRD) template and is consistent with the details registered for the cross-reference product.

The package leaflet for the reference product, Telfast 120mg film coated tablets (PL 04425/0157), has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.
Carton and label
Text versions of the PIL and labelling have been provided; these have been assessed and are satisfactory. In accordance with medicines legislation, the Marketing Authorisation Holder (MAH) has provided a commitment that the product shall not be marketed in the UK until approval of the PIL and label mock-ups has been obtained and assessed.

7. CONCLUSIONS
The data submitted with this application is acceptable. A Marketing Authorisation was, therefore, granted.
NON-CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10c of EC Directive 2001/83 (as amended). This application is identical to the reference product Telfast 120mg film coated tablets (PL 04425/0157) authorised to Aventis Pharma Limited, therefore, no new non-clinical data has been supplied with this application and none are required. A non-clinical overview report has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The marketing authorisation holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As this application is identical to an already authorised reference product, it is not expected that the environmental exposure to fexofenadine hydrochloride will increase following the marketing approval of the proposed product.
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to Telfast 120mg film coated tablets (PL 04425/0157) authorised to Aventis Pharma Limited.

No new clinical data has been supplied with this application and none are required. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.

The marketing authorisation holder (MAH) has provided adequate justification for not submitting a Risk Management Plan (RMP). As this application is identical to an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well-established.

The MAH has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with those previously assessed for the cross-reference product and as such has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is considered identical to the previously granted licence for Telfast 120mg film coated tablets (PL 04425/0157) authorised to Aventis Pharma Limited.

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC, PIL and labelling are satisfactory, and consistent with those for the cross-reference product.

The package leaflet, for the reference product, Telfast 120mg film coated tablets (PL 04425/0157), has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. This application is identical to the reference product. The language used for the purpose of user testing the PIL was English. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

Text versions of the PIL and labelling have been provided these have been assessed and are satisfactory. In accordance with medicines legislation, the Marketing Authorisation Holder (MAH) has provided a commitment that the product shall not be marketed in the UK until approval of the PIL and label mock-ups has been obtained and assessed.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with fexofenadine hydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS
PL 04425/0667

STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 8 July 2010.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 28 July 2010.</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 24 December 2010.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 11 February 2011.</td>
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<td>The application was determined on 17 August 2011.</td>
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STEPS TAKEN AFTER ASSESSMENT

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SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Fexofenadine hydrochloride 120 mg Tablets (PL 04425/0667) is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Fexofenadine hydrochloride 120 mg Film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 120 mg of fexofenadine hydrochloride, which is equivalent to 112 mg of fexofenadine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Film coated tablets.
Peach, modified capsule-shaped, film-coated tablet, debossed with ‘012’ on one side and a scripted ‘e’ on the other side.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Relief of symptoms associated with seasonal allergic rhinitis.

4.2 Posology and method of administration
Adults and children aged 12 years and over
The recommended dose of fexofenadine hydrochloride for adults and children aged 12 years and over is 120 mg once daily taken before a meal.

Fexofenadine is a pharmacologically active metabolite of terfenadine.

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

Special risk groups
Studies in special risk groups (elderly, renally or hepatically impaired patients) indicate that it is not necessary to adjust the dose of fexofenadine hydrochloride in these patients.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use
As with most new drugs there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine hydrochloride should be administered with care in these special groups.

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a drug class, have been associated with the adverse events, tachycardia and palpitations (see section 4.8).
4.5 Interaction with other medicinal products and other forms of interaction
Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other drugs through hepatic mechanisms. Coadministration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse events compared to the drugs given singly.

Animal studies have shown that the increase in plasma levels of fexofenadine observed after coadministration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

No interaction between fexofenadine and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to fexofenadine hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids.

4.6 Pregnancy and lactation

Pregnancy
There are no adequate data from the use of fexofenadine hydrochloride in pregnant women. Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary.

Lactation
There are no data on the content of human milk after administering fexofenadine hydrochloride. However, when terfenadine was administered to nursing mothers fexofenadine was found to cross into human breast milk. Therefore fexofenadine hydrochloride is not recommended for mothers breast feeding their babies.

4.7 Effects on ability to drive and use machines
On the basis of the pharmacodynamic profile and reported adverse events it is unlikely that fexofenadine hydrochloride tablets will produce an effect on the ability to drive or use machines. In objective tests, Fexofenadine hydrochloride has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify sensitive people who have an unusual reaction to drugs, it is advisable to check the individual response before driving or performing complicated tasks.

4.8 Undesirable effects
In adults, the following undesirable effects have been reported in clinical trials, with an incidence similar to that observed with placebo:

Nervous system disorders
Common (≥1/100 to <1/10): headache, drowsiness, dizziness

Gastrointestinal disorders
Common (≥1/100 to <1/10): nausea

General disorders and administration site conditions
Uncommon (≥1/1,000 to <1/100): fatigue

In adults, the following undesirable effects have been reported in post-marketing surveillance. The frequency with which they occur is not known (can not be estimated from available data):

Immune system disorders
hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis

Psychiatric disorders
insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria)
Cardiac disorders
tachycardia, palpitations

Gastrointestinal disorders
diarrhoea

Skin and subcutaneous tissue disorders
rash, urticaria, pruritus

4.9 Overdose
Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine hydrochloride. Single doses up to 800 mg and doses up to 690 mg twice daily for 1 month or 240 mg once daily for 1 year have been administered to healthy subjects without the development of clinically significant adverse events as compared with placebo. The maximum tolerated dose of fexofenadine hydrochloride has not been established.

Standard measures should be considered to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihistamines for systemic use, ATC code: R06A X26

Fexofenadine hydrochloride is a non-sedating H₁ antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine. Human histamine wheal and flare studies following single and twice daily doses of fexofenadine hydrochloride demonstrate that the drug exhibits an antihistaminic effect beginning within one hour, achieving maximum at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing. A positive dose-response relationship between doses of 10 mg to 130 mg taken orally was found to exist. In this model of antihistaminic activity, it was found that doses of at least 130 mg were required to achieve a consistent effect that was maintained over a 24 hour period. Maximum inhibition in skin wheal and flare areas were greater than 80%. Clinical studies conducted in seasonal allergic rhinitis have shown that a dose of 120 mg is sufficient for 24 hour efficacy.

No significant differences in QTc intervals were observed in seasonal allergic rhinitis patients given fexofenadine hydrochloride up to 240 mg twice daily for 2 weeks when compared to placebo. Also, no significant change in QTc intervals was observed in healthy subjects given fexofenadine hydrochloride up to 60 mg twice daily for 6 months, 400 mg twice daily for 6.5 days and 240 mg once daily for 1 year, when compared to placebo. Fexofenadine at concentrations 32 times greater than the therapeutic concentration in man had no effect on the delayed rectifier K+ channel cloned from human heart.

Fexofenadine hydrochloride (5-10 mg/kg po) inhibited antigen induced bronchospasm in sensitised guinea pigs and inhibited histamine release at supratherapeutic concentrations (10-100 μM) from peritoneal mast cells.

5.2 Pharmacokinetic properties
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with Tₘₐₓ occurring at approximately 1-3 hours post dose. The mean Cₘₐₓ value was approximately 427 ng/ml following the administration of a 120 mg dose once daily.

Fexofenadine is 60-70% plasma protein bound. Fexofenadine undergoes negligible metabolism (hepatic or non-hepatic), as it was the only major compound identified in urine and faeces of animals and man. The plasma concentration profiles of fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear for oral doses up to 120 mg BID. A dose of 240 mg BID produced slightly greater than proportional increase (8.8%) in steady state area under the curve, indicating that fexofenadine pharmacokinetics are practically linear at these doses.
between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while up to 10% of ingested dose is excreted unchanged through the urine.

5.3 **Preclinical safety data**  
Dogs tolerated 450 mg/kg administered twice daily for 6 months and showed no toxicity other than occasional emesis. Also, in single dose dog and rodent studies, no treatment-related gross findings were observed following necropsy.

Radiolabelled fexofenadine hydrochloride in tissue distribution studies of the rat indicated 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 tests.

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

In a reproductive toxicity study in mice, fexofenadine hydrochloride did not impair fertility, was not teratogenic and did not impair pre- or postnatal development.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

*Tablet core:*
- Microcrystalline Cellulose
- Pregelatinised Maize Starch
- Croscarmellose Sodium
- Magnesium Stearate

*Film coat:*
- Hypromellose
- Povidone
- Titanium Dioxide (E171)
- Colloidal Anhydrous Silica
- Macrogol 400
- Iron oxide (E172)

6.2 **Incompatibilities**

Not applicable

6.3 **Shelf life**

3 years

6.4 **Special precautions for storage**

This medicinal product does not require any special storage conditions.

6.5 **Nature and contents of container**

PVC/PE/PVDC/Al blisters, packaged into cardboard boxes. 2(sample only), 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package. Not all packs sizes may be marketed

6.6 **Special precautions for disposal**

No special requirements.

7 **MARKETING AUTHORISATION HOLDER**

Aventis Pharma Ltd
50 Kings Hill
West Malling
Kent
ME19 4AH
Or trading as

Sanofi-aventis
One Onslow Street
Guildford
Surrey
GU1 4YS

8 MARKETING AUTHORISATION NUMBER(S)
PL 04425/0667

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
17/08/2011

10 DATE OF REVISION OF THE TEXT
17/08/2011
FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS
PL 04425/0667

PATIENT INFORMATION LEAFLET

INFORMATION FOR THE USER

Fexofenadine hydrochloride 120mg Film-coated tablets
Fexofenadine hydrochloride

Is this leaflet hard to see or read?
In the UK Phone 01483 505515 for help

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fexofenadine is and what it is used for
2. Before you take Fexofenadine
3. How to take Fexofenadine
4. Possible side effects
5. How to store Fexofenadine
6. Further information

1. WHAT FEXOFENADINE IS AND WHAT IT IS USED FOR

Fexofenadine hydrochloride 120mg Film-coated-tablets (called Fexofenadine throughout this leaflet) contains fexofenadine hydrochloride, which is an antihistamine.
Fexofenadine 120 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. BEFORE YOU TAKE FEXOFENADINE

Do not take Fexofenadine

- if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Fexofenadine (see section 6 for a full list of ingredients)

Take special care with Fexofenadine

- if you have problems with your liver or kidneys
- if you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- if you are elderly
If any of these apply to you, or if you are not sure, tell your doctor before taking Fexofenadine.

Taking other medicines

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

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine, by lowering the amount of drug absorbed.
It is recommended that you leave about 2 hours between the time that you take Fexofenadine and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
Do not take Fexofenadine if you are pregnant, unless necessary.
Fexofenadine is not recommended during breast-feeding.

Driving and using machines

Fexofenadine is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. HOW TO TAKE FEXOFENADINE

Always take Fexofenadine exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over

The recommended dose is one tablet (120 mg) daily.
Take your tablet with water before a meal.

If you take more Fexofenadine than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Fexofenadine

Do not take a double dose to make up for a forgotten tablet.
Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Fexofenadine

Tell your doctor if you want to stop taking Fexofenadine before you have finished your course of treatment.
If you stop taking Fexofenadine earlier than planned, your symptoms may return.
If you have any further questions on the use of this product, ask your doctor or pharmacist.
4. POSSIBLE SIDE EFFECTS

Like all medicines, Fexofenadine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Fexofenadine if you experience swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (occurring in less than 1 in 10 but more than 1 in 100 patients): headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but more than 1 in 1,000 patients): difficulty sleeping (insomnia), tiredness/sleepiness, sleeping disorders, bad dreams, nervousness, fast or irregular heart beat and diarrhoea.

Rare side effects (occurring in less than 1 in 1,000 but more than 1 in 10,000 patients): skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat and difficulty breathing.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FEXOFENADINE

Keep out of the reach and sight of children.

Do not use Fexofenadine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

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.

6. FURTHER INFORMATION

What Fexofenadine hydrochloride 120mg Film-coated-tablets contains

The active substance of Fexofenadine is fexofenadine hydrochloride. Each tablet contains 120 mg of fexofenadine hydrochloride.

The other ingredients are:
*Tablet core*: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

*Film coating*: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Fexofenadine hydrochloride 120mg Film-coated-tablets looks like and contents of the pack

Fexofenadine hydrochloride 120mg Film-coated-tablets are peach coloured, capsule shaped tablets marked with “012” on one side and “e” on the other.

Fexofenadine is presented in blister packs. Each tablet is blistered.
Fexofenadine is available in packs of 2 (sample only), 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package.
Not all pack sizes are marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**
In the UK:
Sanoﬁ-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK
Tel: 01483 505515
Fax: 01483 535432
email: uk-medicalinformation@sanoﬁ-aventis.com

*In Ireland:*
Sanoﬁ-aventis Ireland Ltd., Citywest Business
Campus, Dublin 24, Ireland
Tel: 00353 (0) 1 403 5600
Fax: 00353 (0) 1 403 5601
email: IEmedinfo@sanoﬁ-aventis.com

**Manufacturer:**
Sanoﬁ Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37 100 Tours, France

This medicinal product is authorised in the Member States of the EEA under the following names:

- Austria: Telfast 120 mg-Filmtabletten
- Belgium: Allergo Rhinathol 120 mg filmomhulde tabletten
- Denmark: Telfast, filmovertrukne tablett 120 mg
- Finland: Telfast 120 mg tabletti, kalvopäällysteinen
- Germany: Telfast 120 mg-Filmtablirten
- Ireland: Telfast 120 mg film-coated tablets
- Italy: Telfast 120 mg compresse rivestite con film
- Portugal: Telfast 120, comprimidos revestidos por película
- Spain: Telfast 120 mg comprimidos recubiertos con película
- Sweden: Telfast 120 mg filmhärade tablettar
- United Kingdom: Telfast 120 mg film-coated tablets/ Fexofenadine hydrochloride 120mg film-coated tablets

This leaflet was last revised in [month and year]

© Sanoﬁ-aventis, [year]
1. **NAME OF THE MEDICINAL PRODUCT**
   Fexofenadine hydrochloride 120mg Film-coated tablets

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**
   Each tablet contains 120mg fexofenadine hydrochloride.

3. **LIST OF EXCIPIENTS**
   N/A

4. **PHARMACEUTICAL FORM AND CONTENTS**
   30 Film-coated tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**
   For oral use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**
   Keep out of the reach and sight of children.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**
   Read the package leaflet before use.

8. **EXPIRY DATE**
   EXP

9. **SPECIAL STORAGE CONDITIONS**
   N/A

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED**
FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
N/A

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER(s)
Sanofi-aventis,
One Onslow Street,
Guildford,
Surrey,
GU1 4YS
UK

12. MARKETING AUTHORISATION NUMBER(S)
PL 04425/0667

13. BATCH NUMBER
BN

14. GENERAL CLASSIFICATION FOR SUPPLY
POM

15. INSTRUCTIONS ON USE
Read the package leaflet before use.

16. INFORMATION IN BRAILLE
Fexofenadine hydrochloride 120mg Film-coated tablets
PARTICULARS TO APPEAR ON THE INNER PACKAGING

FOIL

1. NAME OF THE MEDICINAL PRODUCT

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Sanofi-aventis logo