## 140 x 280

## Package leaflet: Information for the patient **Numark Hayfever Relief 120mg Film-Coated Tablets** (Fexofenadine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or

has told you.
Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

### What is in this leaflet

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### 1. What Numark Hayfever Relief 120mg Film-Coated Tablets is and what it is used for

Numark Hayfever Relief 120mg Film-Coated Tablets contains Fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Numark Hayfever Relief 120mg Film-Coated Tablets is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hayfever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

#### 2. What you need to know before you take Numark Hayfever Relief 120mg Film-Coated Tablets

Do not take Numark Hayfever Relief 120mg Film-Coated Tablets:

• if you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6).

## Warnings and precautions

Talk to your doctor or pharmacist before taking Numark Hayfever Relief 120mg Film-Coated Tablets if:

- you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- you have problems with your liver or kidneys you are elderly.

If any of these apply to you, or if you are not sure, tell your doctor before taking Numark Hayfever Relief 120mg Film-Coated Tablets.

## Other medicines and Numark Hayfever Relief 120mg Film-Coated Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

Indigestion remedies containing aluminium and magnesium may affect the action of Numark Hayfever Relief 120mg Film-Coated Tablets, by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Numark Hayfever Relief 120mg Film-Coated Tablets and your indigestion remedy.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Numark Hayfever Relief 120mg Film-Coated Tablets if you are pregnant, unless necessary.

Numark Hayfever Relief 120mg Film-Coated Tablets is not recommended during breast-feeding.

### Driving and using machines

Numark Hayfever Relief 120mg Film-Coated Tablets is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets donot make you feel sleepy or dizzy before driving or operating machinery.

# Numark Hayfever Relief 120mg Film-Coated Tablets contains lactose.

Numark Hayfever Relief 120mg Film-Coated Tablets contains lactose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to use Numark Hayfever Relief 120mg Film-Coated Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist as told you. 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 (120mg) daily.

Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours. This medicine is not recommended for children under 12 years of age.

If you take more Numark Hayfever Relief 120mg Film-Coated Tablets 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 Numark Hayfever Relief 120mg Film-Coated Tablets

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

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

Tell your doctor immediately and stop taking Numark Hayfever Relief 120mg Film-Coated Tablets if you experience:

• swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug (placebo).

**Common side effects** (may affect up to 1 in 10 people):

- headache
- drowsiness
- feeling sick (nausea)dizziness.
- uizziiiess.

**Uncommon side effects** (may affect up to 1 in 100 people):

• tiredness/sleepiness.

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:

• difficulty sleeping (insomnia)

- sleeping disorders
- bad dreams
- nervousness
- · fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing
- blurred vision.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

. How to store Numark Hayfever Relief 120mg Film-Coated Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine 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 conditions.
- 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 to protect the environment.

### 5. Contents of the pack and other information

What Numark Hayfever Relief 120mg Film-Coated Tablets contains The active substance is Fexofenadine

#### hydrochloride.

Each film-coated tablet contains 120mg of Fexofenadine hydrochloride.

The other ingredients are: Lactose monohydrate, Low-substituted-Hydroxypropyl Cellulose (E463), Pregelatinised starch, Colloidal anhydrous silica (E551), Microcrystalline cellulose (E460), Croscarmellose sodium (E468), Magnesium stearate (E572), Hypromellose, Povidone, Titanium dioxide (E171), Iron oxide Red (E172), Iron oxide Yellow (E172) and Macrogol 400.

### What Numark Hayfever Relief 120mg Film-Coated Tablets looks like and contents of the pack

Numark Hayfever Relief 120mg Film-Coated Tablets: Peach coloured capsule shaped film-coated tablets, debossed as '120' on one side and 'FX'on other side.

Numark Hayfever Relief 120mg Film-Coated Tablets are provided in blisters of Alu-PVC/PVDC or Alu/PVC/PE/ACLAR in pack size of 7, 10, 15, 20 and 30 tablets.

Not all pack sizes may be marketed.

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To listen to or request a copy of this leaflet in Braille, large print or audio please call, 02033998900 (UK only)

Please be ready to give the following information: Product name Numark Hayfever Relief 120mg Film-Coated Tablets Reference number PL 44041/0233

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