Infographie COMPIÈGNE	Version N° 2	Type Article		Notice simple		N° version Logo/Name N° version Country Ex.	N.A.	sanofi
créé le par	10/06/2024 DERIGNY C	Nom du prod Référence art	1.1	Allevia Hives R400308		N° plan Dimensionnel N° plan positionnement	1-606092	Sulloll
modifié le par	11/06/2024 DERIGNY C	Dosage Quantité	180 mg			Dimensions Taille mini caractères	COM-P606092-1c 150 x 210 mm 8 pts	Code sécurité <b>R400308</b>
Laboratoires Pays	Sanofi Grande-Bretagno	Coule Nbre,	leur re/Réf.	1	NOIR		1 - 1 - 1	Numéro de pages 1/2

# **Allevia®** Hives

# 180 mg tablets

fexofenadine hydrochloride Package leaflet: Information for the user

# sanofi

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 pharmacist have 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

- 1. What Allevia Hives 180mg is and what it is used for
- 2. What you need to know before you take Allevia Hives 180mg
- 3. How to take Allevia Hives 180mg
- 4. Possible side effects
- 5. How to store Allevia Hives 180mg
- 6. Contents of the pack and other information

# 1. What Allevia Hives 180mg is and what it is used for



Allevia Hives 180mg contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Allevia Hives 180mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with allergic skin reactions (chronic idiopathic urticaria) such as red, raised, itchy skin, which is often known as hives or nettle rash.

Allevia Hives 180mg is not suitable for children under 12 years of age

You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

#### What you need to know before you take Allevia Hives 180mg



# Do not take Allevia Hives 180mg

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 Allevia Hives 180mg if you:

- have problems with your liver or kidneys
- are elderly
- have or ever had heart problems, as fexofenadine, like other antihistamines may cause your heart to beat faster (tachycardia) or you feel your heart beating (palpitations).

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist before taking Allevia Hives 180mg.



#### Other medicines and Allevia Hives 180mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important for the following medicines:

- Erythromycin (an antibiotic)
- Ketoconazole (a treatment for fungal infections) 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 Allevia Hives 180mg by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take Allevia Hives 180mg and your indigestion remedy.

# Allevia Hives 180mg with food and drink

Allevia Hives 180mg should be taken before meals with

# 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. Allevia Hives 180mg should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.



# **Driving and using machines**

Allevia Hives 180mg 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.

## Allevia Hives 180mg contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

# 3. How to take Allevia Hives 180mg



Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

# For adults and adolescents aged 12 years and over

The recommended dose is one tablet (180 mg) daily.

Take the tablet with water before a meal

This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

If the symptoms of allergic skin reactions persist, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Do not exceed the stated dose. Do not give to children below 12 years of age.



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## If you take more Allevia Hives 180mg than you should

If you have accidentally taken more than this leaflet recommended, contact the nearest hospital emergency department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you. The most common signs of overdose are dizziness, drowsiness, fatigue and dry mouth.

#### If you forget to take Allevia Hives 180mg

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

If you get any of the following symptoms after taking these tablets you should contact your doctor or pharmacist immediately as these may be signs of a serious allergic reaction:

 swelling of the face, lips, tongue or throat and difficulty breathing

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.

**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
- feel your heart beating (palpitations)
- 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, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard 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.

#### 5. How to store Allevia Hives 180mg

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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 protect the environment.

# 6. Contents of the pack and other information

#### **What Allevia Hives 180mg contains**

- The active substance is fexofenadine hydrochloride. Each tablet contains 180 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 Allevia Hives 180mg looks like and contents of the pack

Allevia Hives 180mg film-coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and a scripted "e" on the other.

Allevia Hives 180mg is presented in blister packs of 2 (sample pack), 10,15, 20 and 30 tablets. Not all pack sizes are marketed.

# **Marketing Authorisation Holder and Manufacturer**

<u>Marketing Authorisation Holder:</u> Sanofi, 410 Thames Valley Park Drive Reading, Berkshire, RG6 1PT, UK

#### **Manufacturers**

Opella Healthcare International SAS 56, route de Choisy 60200 Compiègne France

This leaflet was last revised in June 2024.

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