

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

POLLENTYME FC 5 mg film-coated tablets

Desloratadine

Read all of this leaflet carefully because it contains important information for you

POLLENTYME FC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use POLLENTYME FC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share POLLENTYME FC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What POLLENTYME FC is and what it is used for

POLLENTYME FC contains a medicine called desloratadine

POLLENTYME FC is an antihistamine.

POLLENTYME FC is used to relieve symptoms in adults and adolescents (over 12 years of age) of:

- Allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.
- Urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling).

2. What you need to know before you take POLLENTYME FC

Do not take POLLENTYME FC:

- If you are hypersensitive (allergic) to desloratadine or any of the other ingredients (listed in section 6).
- If you are allergic to any other antihistamines.
- If you suspect you are pregnant, are pregnant or breastfeeding your baby.

Warnings and precautions:

Take special care with POLLENTYME FC:

- If you have kidney or liver problems
- If you plan to have skin allergy tests as you need to stop taking POLLENTYME FC 48 hours before the test to prevent false negative results
- If you are an elderly patient as your dose may have to be adjusted
- If you suffer from epilepsy (fits).
- If you suffer from the following diseases:
 - - emphysema (shortness of breath, with a cough);
 - - prostate problems;
 - - narrow angle glaucoma (high pressure in the eye);
 - - heart problems;

- - medical or family history of seizures

POLLENTYME FC should not be taken for longer than 4 weeks as safety and efficacy have not been established.

Children

POLLENTYME FC is not recommended for use in children under 12 years as safety and efficacy have not been established.

Other medicines and POLLENTYME FC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following:

- Ketoconazole (antifungal treatment)
- Clarithromycin, erythromycin, azithromycin (antibiotics)
- Fluoxetine (antidepressant)
- Cimetidine (used to treat heartburn or indigestion)

POLLENTYME FC with food and drink

POLLENTYME FC must be swallowed whole with a glass of water with or without food.

Pregnancy and breastfeeding

Do not take POLLENTYME FC if you are pregnant, suspect that you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking POLLENTYME FC.

Driving and using machines

It is not always possible to predict to what extent POLLENTYME FC may interfere with your daily activities. POLLENTYME FC may cause sleepiness, dizziness and blurred vision in some patients. Do not drive or operate heavy machines until you know how POLLENTYME FC will affect you.

3. How to take POLLENTYME FC

Always take POLLENTYME FC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosages are as follows:

Adults and children 12 years of age and older: One tablet daily

Patients with mild to moderate liver or kidney impairment: 5 mg (one tablet) every other day as a starting dose

If you take more POLLENTYME FC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The symptoms reported for overdosage in adults and children: are headache, sleepiness and rapid heart rate.

If you forget to take POLLENTYME FC

Do not take a double dose to make up for forgotten individual doses. If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

POLLENTYME FC can have side effects.

Not all side effects reported for POLLENTYME FC are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking POLLENTYME FC, please consult your health care provider for advice.

If any of the following happens, stop taking POLLENTYME FC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to POLLENTYME FC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Low blood pressure
- Rapid or racing heartbeat
- Shortness of breath
- Confusion
- Depression.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Headache
- Ringing ears

- Blurred vision
- Hair loss
- Muscle pain
- Painful periods
- Inflammation of the liver with symptoms such as loss of appetite, stomach pain, fever and fatigue
- Blood disorders
- Sore throat
- Stomach pain, heartburn, vomiting diarrhoea, dry mouth
- Anorexia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of POLLENTYME FC.

5. How to store POLLENTYME FC

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Keep blister in original container to protect from light.
- Do not use after the expiry date stated on the blister or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What POLLENTYME FC contains

- The active substance is desloratadine.
- The other ingredients are Microcrystalline cellulose, partially pregelatinised maize starch, magnesium stearate, colloidal anhydrous silica, opadry blue (03A30735)

What POLLENTYME FC looks like and contents of the pack

POLLENTYME FC DINE tablets are blue, round, biconvex, film-coated tablets with a diameter of approximately 6, 5 mm.

Aluminium Blisters of 15 tablets are packed in a carton in pack sizes of 15, 30 or 100 tablets.

Holder of Certificate of Registration

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