**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed with a doctor's prescription only

# Xofluza

## 40 mg

Film-coated tablets

Each film-coated tablet contains:

baloxavir marboxil 40 mg

Inactive ingredients and allergens: See section 2 "Important information about some of the medicine ingredients" and section 6 "Further information".

- **Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.
- This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
- The medicine is intended for patients above the age of 12.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is used to treat acute uncomplicated flu (influenza) in patients above the age of 12 years who have experienced flu symptoms for less than 48 hours.

Limitations: Influenza viruses are changing over time and therefore factors such as virus type and sub-type, development of resistance or changes in aggressiveness of the virus may reduce the clinical value of antiviral medicines. Information on the medicine susceptibility pattern of the seasonal influenza strains should be considered while making a decision regarding the use of Xofluza.

**Therapeutic group: antiviral medicines.**

Xofluza is an antiviral medicine acting against the influenza virus.

It is not intended to prevent or treat illness that is caused by infections other than the influenza virus and does not prevent bacterial infections that may happen with the flu.

It inhibits the endonuclease enzyme.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- you are sensitive (allergic) to baloxavir marboxil or to any of the other ingredients contained in the medicine (detailed in section 6 – "Further Information").

Special warnings regarding use of this medicine

Contact the doctor, pharmacist or nurse **immediately** if you have a hypersensitivity reaction to the medicine, including:

difficulties breathing, skin rash, urticaria or skin blisters, swelling of the face, throat or mouth, dizziness or lightheadedness.

**Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking certain laxatives, antacids and nutritional supplements such as calcium, iron, magnesium, selenium, zinc.

After taking Xofluza, consult the doctor prior to receiving an attenuated live vaccination.

**Use of the medicine and food**

The medicine can be taken with or without food.

Avoid taking the medicine together with dairy products and calcium – enriched beverages.

**Pregnancy and breastfeeding**

If you are pregnant or planning a pregnancy, consult the doctor or pharmacist before using Xofluza. It is not known whether the medicine may harm the fetus.

If you are breastfeeding or planning to breastfeed, consult the doctor or pharmacist before use. It is not known whether the medicine passes into breast milk.

**Important information about some of the medicine ingredients**

This medicine contains lactose. If you have been told by your doctor that you are sensitive to certain sugars, consult the doctor before taking Xofluza.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine.

There is no information regarding crushing/splitting/chewing.

Treatment with Xofluza should start within 48 hours of the onset of symptoms.

Take the medicine orally as a single and one-time dose.

The dosage and manner of treatment will be determined only by the doctor.

The usual dosage in patients above the age of 12 is:

| Patient body weight (kg) | Recommended dosage |
|---|---|
| 40-80 kg | Single administration of 40 mg |
| Above 80 kg | Single administration of 80 mg |

**Do not exceed the recommended dose.**

**If you accidentally took a higher dosage**

If you accidentally took an overdose or if a child has accidentally swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of this medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Xofluza may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Contact the doctor immediately** if you have a hypersensitivity reaction (allergic reactions) to the medicine, including:

- difficulties breathing
- skin rash, urticaria or skin blisters
- swelling of the face, throat or mouth
- dizziness or lightheadedness.

**Additional side effects**

- diarrhea
- bronchitis
- nausea
- sinusitis
- headache

The following side effects have been identified during post-marketing use of Xofluza.

- Immune system reactions: anaphylactic and anaphylactoid reactions (hypersensitivity); anaphylactic shock, hypersensitivity reactions, angioedema (swelling of face, eyelids, tongue and lips).
- Skin and subcutaneous reactions: rash, urticaria, erythema multiforme.
- Gastrointestinal effects: vomiting, bloody diarrhea, black stool, colitis (inflammation in the colon).
- Psychiatric effects: delirium, abnormal behavior, hallucinations.

Xofluza is not effective in treating infections other than influenza. Other infections may be similar to flu symptoms or appear in combination with flu and will require other type of treatment. Contact your doctor if you experience worsening of your medical condition or develop new symptoms during or after the treatment with Xofluza, or if your flu symptoms are not improving.

**If a side effect occurs, if any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

**Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting side effects following drug treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

## 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the blister and on the package. The expiry date refers to the last day of that month.

Storage conditions: Store below 30°C. Store the medicine in the original package to protect from moisture.

## 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose Monohydrate, Croscarmellose Sodium, Povidone, Microcrystalline Cellulose, Sodium Stearyl Fumarate, Talc, Hypromellose, Titanium Dioxide.

What does the medicine look like and what are the contents of the package?

Xofluza 40 mg film-coated tablets are white to yellowish, oblong tablets with “BXM40” embossed on one side.

The package contains 1 or 2 film-coated tablets.

*Not all pack sizes may be marketed.

**License holder and address:** Roche Pharmaceuticals (Israel) Ltd., 6 Hacharash street, P.O.B. 6391, Hod Hasharon 4524079.

www.roche.co.il

**Manufacturer’s name and address:** F. Hoffmann-La Roche Ltd., Basel, Switzerland.

**This leaflet was revised in January 2023 according to MOH guidelines.**

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

Xofluza 40 mg - 163.38.35956.00