

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Tilade**

### **CFC-Free Inhaler 2mg per actuation pressurised inhalation suspension**

nedocromil sodium

Sanofi Logo

Is this leaflet hard to see or read?

Phone 0845 372 7101 for help

#### **Read all of this leaflet carefully before you start using 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. See section 4.

#### **In this leaflet:**

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

#### **1. What Tilade is and what it is used for**

Tilade CFC-Free Inhaler (called Tilade throughout this leaflet) contains a medicine called nedocromil sodium. Tilade is used to treat asthma.

- It works by helping to stop tissues from swelling
- This helps stop the narrowing of the airways that happens in asthma

Tilade is used to prevent asthma attacks and may be called a ‘preventer’.

- Tilade will not help an asthma attack that has already started
- You will need to use a different inhaler, called a ‘reliever’, for these attacks (see Section 3)

#### **2. Before you use Tilade**

##### **Do not use this medicine and tell your doctor if:**

- x You are allergic (hypersensitive) to nedocromil sodium or any of the other ingredients of Tilade (listed in Section 6).

Signs of an allergic reaction to Tilade include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Tilade.

#### **Take special care with Tilade**

##### **Check with your doctor or pharmacist before taking your medicine if:**

- You are using any other inhalers

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Tilade

### **Using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Tilade can affect the way some other medicines work. Also some medicines can affect the way Tilade works.

In particular, tell your doctor if you are also using a steroid medicine:

- This can be either an inhaler (such as beclometasone) or a tablet (such as prednisolone)
- If you are using a steroid as well as Tilade, your doctor may decide to reduce the amount of steroid taken or gradually stop the steroid altogether

If your steroid treatment has been reduced or stopped and your asthma then gets worse you must tell your doctor straight away. They may wish to increase or re-start the steroid treatment.

### **Pregnancy and breast-feeding**

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or are breast-feeding.

### **Driving and using machines**

Tilade has no known effect on your ability to drive or use any tools or machines.

### **3. How to use Tilade**

Always use Tilade exactly as your doctor has told you. Make sure that you know:

- How to use the inhaler
- When to use it
- How many puffs you should take each time

You should check with your doctor or pharmacist if you are not sure.

### **How much to use**

- The usual starting dose for adults and children over 6 years is 2 puffs four times a day
- Taking puffs at meal times and at bed time may help you to remember to take it
- Your doctor may tell you to take more or less puffs depending on how bad your asthma is. As your asthma gets better, your doctor may suggest that you reduce your daily dose to 2 puffs twice a day. If this happens, use your inhaler in the morning when you wake and again before you go to bed
- Tilade is not recommended for use in children 6 years of age and younger. Check with your doctor or pharmacist before using

### **Using this medicine**

- This medicine may not help your symptoms straight away. You may need to use your inhaler for several weeks for it to work best. It only works if you use it every day, even when you feel well
- Your asthma may get worse if you have an infection, are unwell or come into contact with anything to which you are allergic. If this happens, talk to a doctor straight away. You may need to go to hospital for treatment
- If you have to go to a doctor, dentist or hospital for any reason, tell them that you are using Tilade. Also take all your inhalers and any other medicines you are taking with you (in their packaging if possible)
- It may be helpful to rinse your mouth with water after using the inhaler. This will help stop any unpleasant taste or coughing.

### **Using a 'reliever' inhaler**

- If your doctor has advised you to use a 'reliever' inhaler at the same time as the Tilade inhaler, it is best to use your 'reliever' inhaler before using your Tilade inhaler. This will open the airways and allow the Tilade to get down into them better

- Keep your ‘reliever’ inhaler available at all times in case of a sudden attack or if your asthma gets worse. Talk to your doctor if it takes more puffs than usual from your ‘reliever’ inhaler to control your symptoms

**How to use your inhaler** (An adult should help small children use their inhaler properly)

### 1. Open

Remove the mouthpiece cover and check that the mouthpiece is clean

### 2. Shake

Shake the inhaler well (at least 5 times)

- If you are using this inhaler for the first time, release 4 puffs into the air
- If the inhaler has not been used for more than 3 days, release 2 puffs into the air



### 3. Inhale

- Hold the inhaler upright with your thumb on the base
- Hold the inhaler well away from your mouth
- Breathe out as far as is comfortable
- DO NOT breathe out through the inhaler. This is to stop moisture from collecting and blocking the spray
- Put the mouthpiece in your mouth and close your lips tightly around it
- Start to breathe in **Slowly** and deeply through your mouth then....
- **Immediately** press the metal canister down firmly to release a puff of medicine, while keeping breathing in slowly and deeply



### 4. Hold

- Remove the inhaler from your mouth and hold your breath for about 10 seconds, or as long as is comfortable
- Breathe out slowly



### 5. Repeat

If your doctor has told you to take 2 puffs each time you use your inhaler:

- Wait for one minute after the first puff. Then repeat steps 2 to 4 once more

### 6. Close

After use, always replace the mouthpiece cover to keep out dust and fluff.

### Important things to make sure you are using the inhaler properly

Practice in front of a mirror or with a pharmacist or doctor from time to time. If you see a mist escaping from your mouth or around the sides of the canister you need to try to use your inhaler better:

- Be sure to have your lips closed properly around the mouthpiece
- Be sure to start breathing in before pressing the canister

### If you or a child use more Tilade than you should

If you or a child use more Tilade than you should, talk to a doctor or go to a hospital straight away. However, using too much is unlikely to cause problems.

### If you forget to use Tilade

If you have forgotten to use Tilade, take your next dose as soon as you remember. Do not take a double dose to make up for a dose you have missed.

### **If you stop using Tilade**

Do not stop using Tilade or reduce the number of puffs you take without telling your doctor. If you stop your treatment suddenly your symptoms may come back.

### **How to clean**

It is very important to keep the plastic body of the inhaler clean. This helps to stop the build up of powder. Clean the plastic body at least twice a week. No harm will come from washing the plastic body and mouthpiece cover every day.

#### **1. Remove**

- Take out the metal canister and put it in a safe place
- Take off the mouthpiece cover

#### **2. Wash**

- Wash the plastic body of the inhaler thoroughly in hand-hot water from both ends



- Wash through the top for a minute
- Wash through the bottom for a minute
- Then wash the mouthpiece cover

#### **3. Dry**

- Shake off any water that is left and leave to dry in a clean warm place overnight
- When completely dry, put the metal canister back into the plastic body of the inhaler. Then replace the mouthpiece cover
- If the metal canister will not slide easily into the plastic mouthpiece, press the white rubber cover firmly back down onto the metal canister
- Use the second Tilade inhaler you have been given while the other inhaler is drying

### **If the inhaler becomes blocked**

- Soak the plastic mouthpiece in hand-hot water for 20 minutes before you wash it under the tap from both ends (as above)
- Never try to unblock the inhaler with a pin, as this will damage the inhaler



← Do not put the metal canister into water

← Do not remove the rubber cover from the metal canister

### **4. Possible side effects**

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

#### **Stop using Tilade and see a doctor or go to a hospital straight away if:**

- You have severe wheezing, coughing or breathlessness. Inhaler medicines can sometimes make this happen straight after you use them. If this happens, do not use your Tilade inhaler. Use your “reliever” inhaler instead and contact a doctor straight away. The doctor may decide to prescribe a different treatment for your asthma
- You have an allergic reaction to Tilade. The signs may include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue

#### **Tell your doctor or pharmacist if you have any of these side effects that are well known:**

Very common (affects more than 1 in 10 people)

- Headache
- Feeling or being sick
- Indigestion or stomach pain
- Mild coughing or wheezing

Common (affects 1 to 10 people in a 100)

- Unusual or unpleasant taste

Frequency not known

- Throat irritation or sore throat

### **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:

[www.mhra.gov.uk/yellowcard](http://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 Tilade**

- Keep this medicine in a safe place where children cannot see or reach it.
- Always replace the dust cap after use.
- Do not use Tilade after the expiry date. This is given in two places: on the canister label and on the carton. In both places it is given as EXP followed by the month and the year. The inhaler should not be used after the last day of that month.
- Do not store in a refrigerator or freezer.
- The metal canister is pressurised. Do not expose to temperatures above 50°C and protect it from direct sunlight.
- Do not puncture, break or burn the canister even if it seems empty.
- Do not keep the inhaler if your doctor decides to stop treatment or if it is empty.  
Ask your pharmacist how to dispose of medicines no longer required. Medicines should not be disposed of via wastewater or household waste. These will help to protect the environment.

### **6. Further information**

#### **What Tilade contains**

- The active substance is nedocromil sodium. Each actuation (puff) contains 2mg of nedocromil sodium.
- The other ingredients are povidone K30, macrogol 600, levomenthol and heptafluoropropane (HFA 227)
- This product contains no chlorofluorocarbons.

#### **What Tilade looks like and contents of the pack**

- Tilade is an aluminium canister with a device to measure 112 actuations (puffs)
- Each pack contains either 1 or 2 aerosol canisters
- Each canister comes with a plastic adaptor (inhaler) with a dustcap

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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