

CinnoVex[®]

INTERFERÓN BETA -1a



Please read this leaflet carefully before you start taking CinnoVex®. Since the information is regularly updated, make sure you read the information each time. For more information, contact your doctor or pharmacist.

2

CinnoVex®:

CinnoVex® is available as a pack of four separate doses.

Each one consists of: lyophilized powder for injection, solvent for reconstitution in pre-filled syringe and two needles.

Active ingredient: 30 µg (6 million IU) Interferon beta 1-a

Inactive ingredients: Human serum albumin, Sodium chloride, Sodium dibasic phosphate and Sodium monobasic phosphate.

Clinical Pharmacology:

CinnoVex® is a form of a protein called beta interferon that occurs naturally in the body.

MS is a life-long disease that affects nervous system by destroying the protective covering (myelin) which surrounds nerve fibers. The way CinnoVex® works in MS is not well understood.

Indications:

CinnoVex® is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). This includes people who have had their first symptoms of multiple sclerosis

3

and have an MRI consistent with multiple sclerosis.

CinnoVex® will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.

Efficacy of CinnoVex® in treatment of children has not been well established.

Contraindication:

CinnoVex® is contraindicated in patients with a history of hypersensitivity to interferon beta, or

any other component of the formulation.

Precautions for use:

Tell your healthcare provider before using CinnoVex® if you:

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal behavior
- have or had bleeding problems or blood clots
- have or had low blood cell counts
- have or had liver problems
- have or had seizures (epilepsy)

- have or had heart problems
- have or had thyroid problems
- have or had any kind of autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis, systemic lupus erythematosus, or rheumatoid arthritis
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if CinnoVex® will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with CinnoVex®.
- are breastfeeding or plan to breastfeed. It

is not known if CinnoVex® passes into your breast milk. You and your healthcare provider should decide if you will use CinnoVex® or breastfeed. You should not do both.

- Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Instructions for use:

- Your healthcare provider should show you how to prepare and measure your dose of CinnoVex® and how to inject your CinnoVex®

before you use CinnoVex® for the first time.

- CinnoVex® is given once a week by injection into the muscle (intramuscular injection).
- Your healthcare provider will tell you how much CinnoVex® to inject and how often to inject CinnoVex®. Do not inject more than your healthcare provider tells you to.
- If you miss a dose, you should take your next dose as soon as you remember. You should continue your regular schedule the following week. Do not take CinnoVex® two days in a row.
- Do not change your dose unless your

healthcare provider tells you to.

- Change (rotate) your injection site you choose with each injection. This will help decrease the chance that you will have an injection site reaction.
- Do not inject into an area of the body where the skin is irritated, reddened, bruised, infected or scarred in any way.
- Always use a new, unopened CinnoVex® vial for each intramuscular injection.
- Do not Use CinnoVex® if:
 - The seal of the cap is broken
 - The liquid obtained after reconstitution is

colored or you can see particles floating in it.

Setting up:

- Each individual dose package includes a vial of CinnoVex®, a syringe containing solvent and two needles. It is a good idea to have alcohol swabs and sticking plasters ready.
- Remove the lid of the dose package carefully.

Reconstitution with solvent:

1. After washing your hands, find a safe and hard place for putting medical tools.
2. Slowly remove the red plastic rubber.
3. Keep the end of vial containing lyophilized powder and disinfect the plastic rubber by alcohol.
4. Put one of the needles onto the pre-filled syringe. Pull the protective cover off the needle and then put the needle of the pre-filled syringe through rubber inside the vial.
5. Gently inject the full content of the syringe

into vial.

Caution: Rapid addition of the solvent may cause foaming, making it difficult to withdraw CinnoVex®.

6. Keeping the syringe attached to the vial, gently swirl the vial until all the powder has dissolved. Avoid shaking the vial vigorously since this will produce a froth. Discard the vial if the solution appears cloudy, or if you can see particles floating in it.
7. Push the plunger fully into the syringe to remove air.
8. Slowly pull the plunger back until all the

liquid is in the syringe.

9. Open the wrapping of the extra needle to expose the connection port. Keep the protective cover over the needle and set it aside while processing step in no. 10.
10. Hold the base of the syringe and remove it from the vial. *Do not touch the connection part.*
11. Put the extra needle onto the syringe.
12. Pull the protective cover off the needle and keep it nearby.
13. Turn the syringe and needle upside down.
14. To remove air, gently tap the syringe to

bring the bubbles up. Slowly push the plunger to remove air without expelling more than a small drop of liquid.

15. Replace the needle cover and set it aside till the injection site is prepared.

Injection:

1. The injection site should be chosen and cleaned with a new alcohol swab before injection.
2. Remove the plastic needle cover and insert the needle through the skin into the muscle.

3. Inject slowly and remove the syringe.
4. If necessary, apply a sticking plaster to the site of injection.

Disposing of the rubbish properly:

Put the needle, syringe, and vial into a sharps container.
Waste paper and used swabs can be put in an ordinary rubbish bin.

Warnings:

Tell your healthcare provider right away if you have any of the symptoms listed below while

taking CinnoVex[®]:

- Behavioral health problems including depression, suicidal thoughts or hallucinations.
- Some people taking CinnoVex[®] may develop mood or behavior problems including:
- irritability (getting upset easily)
 - depression (feeling hopeless or feeling bad about yourself)
 - nervousness
 - anxiety
 - aggressive behavior
 - thoughts of hurting yourself or suicide
 - hearing or seeing things that others do

not hear or see (hallucinations)

- Liver problems, or worsening of liver problems including liver failure and death. Symptoms may include:
 - nausea
 - loss of appetite
 - tiredness
 - dark colored urine and pale stools
 - yellowing of your skin or the white part of your eye
 - bleeding more easily than normal
 - confusion
 - sleepiness

During your treatment with CinnoVex® you will need to see your healthcare provider regularly and have regular blood tests to check for side effects.

- Serious allergic reactions and skin reactions. Symptoms may include:
 - itching
 - swelling of the face, eyes, lips, tongue or throat
 - trouble breathing
 - anxiousness
 - feeling faint
 - skin rash, hives, sores in your mouth, or

your skin blisters and peels

- Heart problems, including heart failure. While CinnoVex® is not known to have any direct effects on the heart, a few patients who did not have a history of heart problems developed heart muscle problems or congestive heart failure after taking CinnoVex®. If you already have heart failure, CinnoVex® may cause your heart failure to get worse. Call your healthcare provider right away if you have worsening symptoms of heart failure such as shortness of breath or swelling of your lower legs or feet while using CinnoVex®.

- Some people using CinnoVex® may have other heart problems including:
 - low blood pressure
 - fast or abnormal heart beat
 - chest pain
 - heart attack or a heart muscle problem (cardiomyopathy)
- Blood problems
CinnoVex® can affect your bone marrow and cause low red and white blood cell, and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you

can get infections and problems with bleeding and bruising.

- Seizures

Some patients have had seizures while taking CinnoVex®, including patients who have never had seizures before.

- Infections. Some people who take CinnoVex® may get an infection. Symptoms of an infection may include:

- fever
- chills
- pain or burning with urination
- urinating often

- bloody diarrhea
- coughing up mucus
- Thyroid problems. Some people taking CinnoVex® develop changes in their thyroid function. Symptoms of thyroid changes include:

- problems concentrating
- feeling cold or hot all the time
- weight changes (gain or loss)
- skin changes

Side effects:

- Flu-like symptoms. Most people who take

CinnoVex® have flu-like symptoms early during the course of therapy. Usually, these symptoms last for a day after the injection. You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers. For many people, these symptoms lessen or go away over time. Symptoms may include:

- muscle aches
- fever
- tiredness
- chills

Storage instructions:

- Keep CinnoVex® unopened at 2-8°C. Do not store in the freezer.
- CinnoVex® should not be frozen or exposed to high temperature.
- The reconstituted solution (once in the syringe) can be stored at 2-8°C for up to 3 hours prior to injection. The reconstituted solution should not be frozen or exposed to high temperature.
- The shelf-life of CinnoVex® (Interferon beta-1a) is 24 months.
- You should not use the product after the



expiry date on the label. The first two numbers indicated the month after which the product can no longer be used, and the last four numbers indicate the year of expiry.

- Keep CinnoVex® out of the reach of children.

General advice :

- Do not use CinnoVex® for a condition for which it was not prescribed.
- Do not give CinnoVex® to other people, even if they have the same symptoms that you have, it may harm them.
- This Medication Guide summarizes the most

important information about CinnoVex®. If you would like more information, talk with your healthcare provider.



