

APO-CICLOSPORIN

CICLOSPORIN

Consumer Medicine Information

This leaflet provides important information about using APO-CICLOSPORIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-CICLOSPORIN.**

Where to find information in this leaflet:

1. Why am I using APO-CICLOSPORIN?
2. What should I know before I use APO-CICLOSPORIN?
3. What if I am taking other medicines?
4. How do I use APO-CICLOSPORIN?
5. What should I know while using APO-CICLOSPORIN?
6. Are there any side effects?
7. Product details

1. Why am I using APO-CICLOSPORIN?

APO-CICLOSPORIN contains the active ingredient ciclosporin. APO-CICLOSPORIN is an immunosuppressive agent. These medicines help to control your body's immune system.

APO-CICLOSPORIN is used for people who have had a kidney, heart or liver transplant, to prevent the body from rejecting the new organ. It does this by blocking the development of special cells which would normally attack the transplanted tissue.

APO-CICLOSPORIN is also used to treat several other conditions which are thought to be caused by a problem with the immune system:

- a kidney disease called nephrotic syndrome
- severe cases of rheumatoid arthritis (a disease, affecting the joints with pain and swelling)
- severe cases of:
 - psoriasis (a skin disease with thickened patches of red skin, often with silvery scales)
- atopic dermatitis (skin allergies)

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason. APO-CICLOSPORIN is only available with a doctor's prescription. It is not addictive.

2. What should I know before I use APO-CICLOSPORIN?

Warnings

Do not use APO-CICLOSPORIN if:

- you are allergic to ciclosporin, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- APO-CICLOSPORIN has passed the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.
- Do not give APO-CICLOSPORIN to a child under 16 years of age to treat severe rheumatoid arthritis, psoriasis or

atopic dermatitis.

There is not enough information to recommend its use for these diseases in children under 16 years of age.

However, APO-CICLOSPORIN can be used in children younger than 16 who have had an organ transplant or who have nephrotic syndrome.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

If you have been prescribed APO-CICLOSPORIN for nephrotic syndrome, rheumatoid arthritis, psoriasis or atopic dermatitis, tell your doctor if you also have any of these health problems/medical conditions:

- high blood pressure that is not controlled
- any uncontrolled infection
- a poorly functioning immune system
- problems with your kidneys or liver
- severe heart, lung or blood vessel disease
- any type of cancer, including skin cancer

Your doctor may not want you to take APO-CICLOSPORIN or may want to take special precautions if you have any of these conditions.

If you are being treated with APO-CICLOSPORIN for psoriasis or atopic dermatitis, you should not concurrently receive UVB-rays or phototherapy.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Experience with APO-CICLOSPORIN in pregnancy is very limited. The use of immunosuppressant medicines, including ciclosporin, during pregnancy has been shown to increase the risk of problems in the mother and the unborn child. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and risks of taking it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breast-feeding is not recommended since ciclosporin, the active ingredient in APO-CICLOSPORIN, passes into breast milk and may affect your baby.