

Consumer Medicine Information

This leaflet provides important information about using SUNITINIB. **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 SUNITINIB.**

Where to find information in this leaflet:

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

1. Why am I using ARX-SUNITINIB?

ARX-SUNITINIB contains the active ingredient sunitinib.

ARX-SUNITINIB is an indolinone derivative and tyrosine kinase inhibitor with potential antineoplastic activity. It interferes with the growth of cancer cells, which are eventually destroyed.

ARX-SUNITINIB is used for treatment of

- **advanced renal cell carcinoma (RCC), a type of renal cancer**
- **gastrointestinal stromal tumour (GIST) GIST is a cancer of the stomach and bowels. It is caused by the uncontrolled growth of cells in the wall of the stomach or bowel. ARX-SUNITINIB slows down the growth of these cells.**
- **pancreatic neuroendocrine tumours. This is a rare cancer in the cells of the pancreas that release hormones.**

Ask your doctor if you have any questions about why ARX-SUNITINIB has been prescribed for you.

Your doctor may have prescribed it for another purpose.

ARX-SUNITINIB is only available with a doctor's prescription. It is not addictive.

Use in children

The safety and efficacy of ARX-SUNITINIB have not been established in children.

2. What should I know before I use ARX-SUNITINIB?

Warnings

Do not use ARX-SUNITINIB if:

- you are allergic to sunitinib or any of the ingredients listed at the end of this leaflet.
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- Do not use ARX-SUNITINIB after the expiry date printed on the pack.
- Do not use ARX-SUNITINIB if the packaging shows signs of tampering.

Check with your doctor if you:

- **have high blood pressure**

- **have or have had an aneurysm (abnormal balloon-like swelling in the wall of an artery)**
- **have problems with your heart**
- **have or have ever had problems with your liver or kidneys**

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?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. ARX-SUNITINIB should not be used during pregnancy. Your doctor will discuss the risks with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not breastfeed while taking ARX-SUNITINIB.