

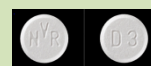


## WHAT IS VOTUBIA® ÉVÉROLIMUS ?

- Immunosuppressant used in adults and children's treatment of the kidney angiomyolipoma (AR) or of the subependymal astrocytoma with giant cells (SEGA) associated with a Bourneville tuberous sclerosis (STB)
- Prescribed and renewed by your doctor experienced in the responsibility for patients showing an STB.
- Available in hospital pharmacy on presentation of your prescription.

Several presentations are available :

- Tablets dosed at **2,5 mg, 5 mg, or 10 mg**
- Dispersible tablets dosed at **2mg, 3mg, or 5mg**



- Store at a temperature not over 30°C, out of reach and sight of children.



- Do not take the tablets out of their box to put them in a pill-box.

- Wash your hands carefully before and after each handling of the tablets.



- Do not throw away the opened boxes, please bring them back to your pharmacist.


## HOW TO TAKE THIS MEDICINE?



To be filled with the  
help of healthcare\*\*

Informed on

Following prescription  
dated  
...../...../.....

<b>Dose per day</b>	..... mg	=	..... tablet (s)
<b>When?</b>	.....h.....	<b>ONE take a day, at fixed hour, during or away from a meal, in continuation</b>	
<b>How ?</b>		Swallow the tablets whole, with water, in succession. The dispersible tablets can be dissolved in water (during 3 minutes). Do not chew, nor cut or crush the tablets	

You can help yourself with **your tracking book and a calendar** to spot the takes. Never stop or change the rhythm of administration of your treatment without your doctor's advice.

\*\* This file is not a prescription ; refer to your latest prescription..

## WHAT TO DO IN CASE OF MISSING OR VOMITING?

- **In case of missing**, do not take the missed dose, nor a double dose. The next dose will be taken at the usual hour, without doubling it. Please note it in your tracking book\*.
- **In case of vomiting**, do not take a new dose. The next dose will be taken at the usual hour, without doubling it. Please note it in your tracking book\*.



## INTERACTIONS WITH OTHER MEDICINES AND/OR FOOD



Check with your **doctor and your pharmacist** that the medicines (with or without **prescription**) and/or **other substances (food, plants, among which grapefruit and St John's Wort**, probiotics, essential oils, food supplements...) that you are taking are compatible with your treatment . Some interactions may have an influence on the efficiency of your treatment or on the outcome of side effects..










- You and your partner must use highly efficient contraceptive methods during the whole treatment and up to 8 weeks after the last take.
- Stop breast feeding during the treatment and up to 2 weeks after the last take.

\*Tracking book available on the sites [www.omeditbretagne.fr](http://www.omeditbretagne.fr) or [www.omedit-paysdelaloire.fr](http://www.omedit-paysdelaloire.fr)

## WHAT SIDE EFFECT MAY OCCUR WITH VOTUBIA® ÉVÉROLIMUS ?

Like all medicines, évérolimus may bring about side effects, although you may not experience any.

Side effects	Prevention
 Mouth inflammation	Maintain a good oral hygiene ( <i>soft toothbrush, non-abrasive, menthol-free toothpaste</i> ). See that you hydrate your lips (ask your pharmacist for advice, especially if you have an oxygenotherapy treatment), and have regular stimulation of saliva ( <i>ice-cubes, chewing-gum...</i> ) and make regular mouth wash with sodium bicarbonate 4 to 6 times a day. Favor fragmented feeding. Favor blended food and drink. Avoid alcohol, coffee, tobacco and irritating food.
 Signs of infection : fever, shivering, cough, sore throat, urinary burns	Limit contacts with people with a contagious infection. Wash your hands frequently. Disinfect any wound carefully. If you have a fever over 38°C, call your doctor.
 Nauseas, vomiting, loss of appetite	Eat slowly and make several small light meals. Avoid greasy, fried and spicy food. Rather drink between meals.
 Diarrhea	Remember to hydrate well : at least 2 litres of water a day. Favor food that is poor in fibers (starchy food, carrots, bananas...). Avoid some food (coffee, frozen drinks, dairy, alcohol, raw fruit and vegetables, cereals, fat food, spices...). Rather drink between meals. Watch over your weight regularly.
 Skin eruption	Use a mild, perfume-free soap and a hydrating agent ( <i>cream or milk</i> ). Avoid hot water. Dab your skin dry. Avoid exposure to the sun (protecting clothes, hat, sun cream ≥50). Inform your doctor in case of skin trouble.
 Nose bleedings, haemorrhages, bruises	In case of nose bleeding, tilt your head forward and blow your nose until draining the blood clots. Press your nostrils slightly for about 10 minutes. Some hemostatic products can be used to reduce the time of compression ( <i>cotton packs to be applied 2 or 3 minutes after pressing and left in for 30 minutes</i> ). Use a soft toothbrush to avoid mouth bleedings. Avoid using a rectal thermometer. Do not take aspirin, nor any anti-inflammatory (ex : ibuprofen) without medical advice.
 Fatigue, headaches, insomnia	Favor healthy feeding, and remember to hydrate well. Respect moments of rest during the day, but try to remain active, even moderately ( <i>walking</i> ). Be prudent if you have to drive. In case of important pains, contact your doctor to set up a symptomatic treatment.
High blood pressure	Take regular measures of your blood pressure ( <i>at home or at the pharmacy</i> ). Take exercise, check your weight. Limit your consumption of salt and alcohol.

Only some of the most frequent side effects are mentioned above. For further information, refer to your packaging or ask your doctor or pharmacist for advice.



You can also ask your questions to your center for side effects monitoring, or notify any side effect on the following site : [signalement-sante.gouv.fr](http://signalement-sante.gouv.fr)



In all cases, do not forget to make the biological test prescribed by your doctor.

## WHAT TO DO IN CASE OF SIDE EFFECT(S) ?

- Take the medication prescribed for side effects, in accordance with the doses.
- Respect measures of prevention.

Useful contacts :

**Promptly contact your doctor** in case of :

- Signs of infection (fever, cough, shivering...)
- Bleedings, black motions, blood-stained spittings
- Shortness of breath, dizziness,, pain in the chest
- Pain, redness or swelling in the legs
- Any persisting or worsening side effect



Remarks :