

Patient Information
VISTOGARD (VIS-toe-gard)
(uridine triacetate)
oral granules

What is VISTOGARD?

VISTOGARD is a prescription medicine that contains uridine, a substance that is normally found in your body. VISTOGARD is used for emergency treatment of adults and children:

- after an overdose of fluorouracil or capecitabine with or without symptoms, **or**
- who have early signs of severe or life-threatening side effects that affect the heart, or early signs of severe or life threatening neurologic (central nervous system) problems, or certain unusually severe side effects within 4 days (96 hours) after receiving treatment with fluorouracil or capecitabine

VISTOGARD should only be used for the emergency treatment of side effects of fluorouracil or capecitabine, because it may decrease the effectiveness of these medicines.

It is not known if VISTOGARD is safe and effective if started more than 4 days (96 hours) after the end of a dose of fluorouracil or capecitabine.

Before taking VISTOGARD, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if VISTOGARD will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VISTOGARD passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VISTOGARD.

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

How should I take VISTOGARD?

- Take VISTOGARD exactly as prescribed by your healthcare provider.
- It is important that you take all 20 doses of VISTOGARD even if you feel well.
- VISTOGARD comes in single-dose packets that contain 10 grams of orange-flavored granules.
- If your healthcare provider decides that you can give VISTOGARD to your child at home, it is important that you follow your healthcare provider's instructions. Your healthcare provider will prescribe VISTOGARD to your child based on your child's weight.
- The usual adult dose of VISTOGARD is 1 packet taken by mouth every 6 hours for a total of 20 doses.
- If you vomit within 2 hours of taking a dose of VISTOGARD, take another full dose as soon as possible. Then take your next VISTOGARD dose at your next regularly scheduled time.
- If you miss a dose of VISTOGARD at the scheduled time, take the missed dose as soon as possible. Then take the next dose at the regularly scheduled time.

Preparing and taking a dose of VISTOGARD:

- Mix each packet of VISTOGARD granules with 3 to 4 ounces of soft food such as applesauce, pudding or yogurt in a small container.
- Take all of the VISTOGARD granules mixed with food within 30 minutes of mixing.
- Do not chew the VISTOGARD granules.
- Drink at least 4 ounces of water to make sure that you swallow all of the medicine.

What are the possible side effects of VISTOGARD?

Common side effects of VISTOGARD include: vomiting, nausea, and diarrhea.

These are not all the possible side effects of VISTOGARD.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VISTOGARD?

- Store VISTOGARD at room temperature between 68°F to 77°F (20°C to 25°C)

Keep VISTOGARD and all medicines out of the reach of children.

General information about the safe and effective use of VISTOGARD.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VISTOGARD for a condition for which it was not prescribed. Do not give VISTOGARD to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VISTOGARD that is written for health professionals.

What are the ingredients of VISTOGARD?

Active Ingredient: uridine triacetate

Inactive Ingredients: ethylcellulose, Opadry Clear [proprietary dispersion of hydroxypropylmethylcellulose and Macrogol], and natural orange juice flavor.

Manufactured for and distributed by: BTG International Inc., West Conshohocken, PA, 19428



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For more information, go to www.vistogard.com or call 1-877-377-3784