

Patient instructions study medication PERSuADER study

Here you can find information about the preparation and use of the PERSuADER study medication. In the week of your surgery, you will be asked to take two antimicrobial solution which together are called SDD or selective decontamination of the digestive tract. How to take the study medication will be explained in this document.

What does the study medication (SDD) look like, and what is in the box?

You will receive two boxes with antimicrobial solutions. The 2 boxes are similar, and both contain two different bottles and one dosing syringe.

- Bottle 1 (brownish bottle with orange milky liquid): contains 40 ml of an antifungal compound, named *Fungizone*. This bottle is labeled as “Fungizone 100 mg/ml suspension for oral use” (active ingredient: Amphotericin B).
- Bottle 2 (transparent bottle with clear liquid): contains 40 ml of an antibiotic suspension, named *basis for the SDD solution*. This bottle is labeled as “Basis for the SDD solution” (active ingredients: Tobramycin and Colistin).

Note: use only if the liquid is clear.

During the week surrounding your surgery, you will have to take 5 ml from both bottles four times a day. Please start with the intake of the *Fungizone* liquid (the brown bottle).

Taking in the antimicrobial solutions (SDD)

Step 1: Shake both bottles well before use.

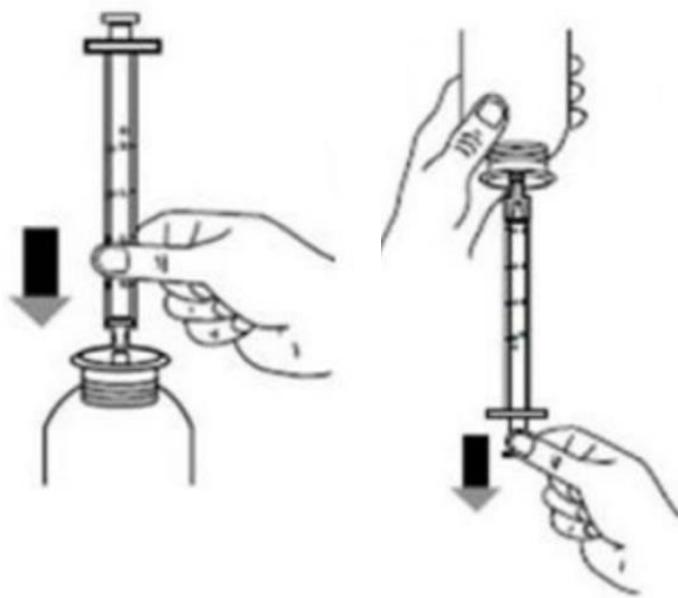
Step 2: Remove the cap from the dosing syringe.

Step 3: Open the brown bottle containing the antifungal solution, *Fungizone* (bottle 1).

Step 4: Place the syringe-coupling piece in the of the brown bottle with the *Fungizone* solution.



Step 5: Measure 5 mL of the *Fungizone* using the provided dosing syringe. You can do this by inserting the syringe into the syringe-coupling piece and drawing up 5 mL into the syringe.



Step 6: Take in the 5 mL of Fungizone liquid orally by emptying the syringe into your mouth and swallowing it.

Step 7: Close the bottle.

Step 8: Rinse the syringe with water under the tap.

Step 9: Next, open the bottle containing the *basis for SDD solution* (bottle 2).

Step 10: Measure 5 mL using the provided dosing syringe. Insert the syringe into the designated opening of the bottle cap. Then, turn the bottle upside down and draw up 5 mL into the syringe.

Step 11: Take in the 5 mL of the base for SDD liquid orally by emptying the syringe into your mouth and swallowing it.

Step 12: Close the bottle.

Step 13: Rinse the syringe with water under the tap.

Step 14: Store everything in the original packaging.

Step 15: Record the time of intake and the amount of mL taken from both liquids in your patient diary and answer the remaining questions in the diary at the end of the day.

Dosage and timing of study medication:

- During the three days prior to your surgery, take: 5 ml of both liquids orally four times a day. It is recommended to take the study medication in intervals of 4 to 6 hours, for example at: 08h00, 12h00, 18h00, 22h00

- On the day of the surgery, take only a dose of 5 ml of both liquids in the morning and late evening.
- During the three days after your surgery, resume taking 5 ml of both liquids orally four times a day.

-

<u>Day -3</u>	<u>Day -2</u>	<u>Day -1</u>	<u>Day of the operation</u>	<u>Day +1</u>	<u>Day +2</u>	<u>Day +3</u>
4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>	4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>	4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>	2 times <u>1 dose before the operation</u> <u>1 dose after the operation</u>	4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>	4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>	4 times <u>08h00</u> <u>12h00</u> <u>18h00</u> <u>22h00</u>

Is there medication that is incompatible with this study?

Sucralfate, which is a medication to treat gastro-esophageal reflux disease (GERD), diminishes the effectiveness of our study medication and should therefore be avoided.

Have you taken too much of the medicine?

If you have accidentally taken too much of either the antifungal or antibiotic solution, contact your treating physician.

Did you forget to take a dose?

Do not take a double dose to make up for a missed one. Instead, make a note in your patient diary that you missed a dose.

If you stop taking the study medication:

You may decide to stop taking the study medication at any time. However, we kindly ask you to notify your treating physician of this event and make a note of this in your patient diary.

Instructions for storage:

Store below 25°C, the solution does not need to be kept in the refrigerator or freezer. The study medication should be kept in its original packaging to keep it from light

Note: Keep out of reach of children.

We ask you to return both the empty vials and the vials with leftover study medication to a nurse on the ward at hospital admission for your surgery.

For further information, please consult the medication information leaflet. If you have additional questions, feel free to contact the research team at:

Mail : PERSuaDER@uzleuven.be

Tel. : +32 (0) 16 345857