Patient Diary

Patient diary version 1.2 - 28-04-2025

Dear Sir/Madam,

Throughout the week in which your surgery is planned, starting from three days before the surgery, we ask you to complete this patient diary.
The intention is for you to report about any problems or discomforts that arise during this period and how they evolve.
If ever you wish to change an answer, you can do so by crossing out the original box ☒ and ticking the new one. ☒
In case of assignment to the group with the trial medication, please also note the date, time and the quantity taken (in milliliters) at every ingestion, as well as any problems experienced with it.

It is important for us that you answer the questions truthfully in order to correctly evaluate the usage of the trial medication.

On admission to the ward, please bring your empty vials and any remaining trial medication and hand these over to the staff.
Thank you in advance for your cooperation.

The PERSuaDER study team
Tel.nr.: +32 (0) 16 345857

Study number: __ __ __ - __ __ __

Protocol nummer: EU CT ID: 2023-504144-33-00

Day 1, this is three days before the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.

Quantity (ml):		**Time of ingestion:**
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: --- --- ---
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: --- --- ---
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: --- --- ---
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: --- --- ---

Did you experience any problems in taking the trial medication? ☐ yes ☐ no

If yes, which ones? ---

Day 2, this is two days before the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.		
Quantity (ml):		**Time of ingestion:**
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Did you experience any problems in taking the trial medication?		☐ yes ☐ no
If yes, which ones? ------------------------------------ ------------------------------------ ------------------------------------		

Day 3, this is one day before the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.		
Quantity (ml):		**Time of ingestion:**
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ____ mL	**Basis for SDD** ____ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Did you experience any problems in taking the trial medication?		☐ yes ☐ no
If yes, which ones? ------------------------------------ -- --		

Day 4, this is the day of the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.

Quantity (ml):		**Time of ingestion:**
Ampho-tericin B	**Basis for SDD**	Time: __:___
mL	mL	☐ Dose not taken, reason:

Ampho-tericin B	**Basis for SDD**	Time: __:___
mL	mL	☐ Dose not taken, reason:

The second dose may have been administered without your noticing; you may ask the nurse if the dose was given and at what time.

Did you experience any problems in taking the trial medication? ☐ yes ☐ no

If yes, which ones? ----------

Day 5, this is one day after the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.		
Quantity (ml):		**Time of ingestion:**
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Did you experience any problems in taking the trial medication?		☐ yes ☐ no
If yes, which ones? ------------------------------------ ------------------------------------ ------------------------------------		

Day 6, this is two days after the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.		
Quantity (ml):		**Time of ingestion:**
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Ampho-tericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Did you experience any problems in taking the trial medication?		☐ yes ☐ no
If yes, which ones? ------------------------------------ ------------------------------------ ------------------------------------		

Day 7, this is three days after the operation:

Please indicate which of the following symptoms you experienced today, and in what way these problems differ from yesterday, by ticking the corresponding boxes.

Complaint:	New	Decrease	Status quo	Increase
☐ Nausea	☐	☐	☐	☐
☐ Itching	☐	☐	☐	☐
☐ Vomiting	☐	☐	☐	☐
☐ Muscle weakness	☐	☐	☐	☐
☐ Diarrhea	☐	☐	☐	☐
☐ Tingling or numb feeling around mouth, lips or face	☐	☐	☐	☐
☐ Bloating	☐	☐	☐	☐
☐ Headache	☐	☐	☐	☐
☐ Abdominal pain	☐	☐	☐	☐
☐ Reduced appetite	☐	☐	☐	☐
☐ Skin rash	☐	☐	☐	☐
☐ No symptoms				
☐ Other: ----------	☐	☐	☐	☐
----------	☐	☐	☐	☐
----------	☐	☐	☐	☐

Date of today: __ - __ - ____

Complete the questions below only if you have been assigned to the group receiving the trial medication.

Quantity (ml):		Time of ingestion:
Amphotericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Amphotericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Amphotericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------
Amphotericin B ☐ mL	**Basis for SDD** ☐ mL	Time: __:___ ☐ Dose not taken, reason: ------------------------------------ ------------------------------------ ------------------------------------

Did you experience any problems in taking the trial medication? ☐ yes ☐ no

If yes, which ones? ------------------------------------
