

<div style="text-align: center;">Sanofi</div> <div style="text-align: center;"><i>PACKAGING TEAM</i></div>		
Code:	769726	Technical Data
Update:	V06 - 14-12-2020	
GMID code:	618678 - 761187	
Current item code:	4827471A	
Product/Item type:	Istruzione Entergermina 2 MLD	
Country:	Export	
Artwork by:	Origgio	
Plant:	Origgio	
GDO - Graphic Department Origgio		
Sanofi S.p.A. - Viale Europa, 11 - 21040 Origgio (VA) - Italy		
Tel. +39 - 02 96 10 559		

Impianti di proprietà *Sanofi S.p.A.*

Vietata la manomissione - **Renderre dopo la stampa**

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Country:	Export
Artwork by:	Origgio
Plant:	Origgio

For Sanofi use only

Format:	Stesa 370x155 mm. - Prepregata 166x155 mm.
Plant barcode:	1740
Number of Colours:	1
■ Pantone Blue REFLEX	
Fonts:	Futura Light Cond. / Light Cond. Oblique / Bold Bold Oblique
Minimum point size of text:	6 pt
Layout of Cutting:	N.A.
Packaging Line:	EG 096
GDO - Graphic Department Origgio	
Sanofi S.p.A. - Viale Europa, 11 - 21040 Origgio (VA) - Italy Tel. +39 - 02 96 10 559	

Technical Data

Impianti di proprietà *Sanofi S.p.A.*

Vietata la manomissione - Rendere dopo la stampa

La prise correcte et scrupuleuse du médicament favorise son efficacité.

Si vous arrêtez de prendre Enterogermina

Aucun effet particulier n'a été signalé, en dehors de l'absence d'effet thérapeutique.

Si vous avez d'autres questions sur l'utilisation de ce médicament, demandez plus d'informations à votre médecin ou à votre pharmacien.

4. QUELS SONT LES EFFETS INDESIRABLES EVENTUELS

Comme tous les médicaments, ce médicament peut provoquer des effets indésirables, mais ils ne surviennent pas systématiquement chez tout le monde.

Effets indésirables de fréquence indéterminée (pouvant affecter moins de 1 personne sur 10 000) :

Des cas de réactions allergiques (hypersensibilité), notamment rougeur de la peau, urticaire et angioedème, ont été rapportés. Si vous prenez Enterogermina et que les mécanismes de défense de votre organisme sont altérés (particulièrement diminués), le *Bacillus clausii* pourra être détecté dans votre sang.

Déclaration des effets secondaires

Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin, votre pharmacien ou votre infirmier/ère. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. En signalant les effets indésirables, vous contribuez à fournir davantage d'informations sur la sécurité du médicament.

5. COMMENT CONSERVER ENTEROGERMINA

TENIR CE MÉDICAMENT HORS DE LA VUE ET DE LA PORTÉE DES ENFANTS.

N'utilisez pas ce médicament après la date de péremption indiquée sur l'emballage après « EXP. ». La date de péremption fait référence au dernier jour de ce mois. Cette date de péremption n'est valable que si le produit est correctement conservé dans son conditionnement intact.

À conserver à une température ne dépassant pas 30°C.

Ne jetez aucun médicament au tout-à-l'égout ou avec les ordures ménagères. Demandez à votre pharmacien d'éliminer les médicaments que vous n'utilisez plus. Ces mesures contribueront à protéger l'environnement.

6. INFORMATIONS SUPPLEMENTAIRES

Enterogermina 2 milliards/5 ml, suspension buvable en flacon content :

- La substance active est : spores de *Bacillus clausii* polyantibiorésistantes. Chaque flacon contient 2 milliards de spores de *Bacillus clausii* polyantibiorésistantes (souches S/N, O/C, T, N/R).
- L'autre composant est l'eau purifiée.

Enterogermina 2 milliards en gélules content :

- La substance active est : spores de *Bacillus clausii* polyantibiorésistantes. Chaque gélule contient 2 milliards de spores de *Bacillus clausii* polyantibiorésistantes (souches S/N, O/C, T, N/R). Les autres composants sont : kaolin lourd, cellulose microcristalline, stéarate de magnésium, gélatine, dioxyde de titane [E171], eau purifiée.

Qu'est-ce que Enterogermina et contenu de l'emballage extérieur

Enterogermina 2 milliards/5 ml, suspension buvable en flacon

Enterogermina se présente sous forme de suspension buvable. Boîte de 10 ou 20 flacons de 5 millilitres.

Enterogermina 2 milliards en gélules

Enterogermina se présente sous forme de gélule. Boîte de 12 ou 24 gélules.

Toutes les présentations peuvent ne pas être commercialisées dans votre pays.

Titulaire de l'autorisation de mise sur le marché

Sanofi S.p.A.
Viale L. Bodio, 37/b
20158 Milan, Italie

Fabricant

Sanofi S.p.A.
Viale Europa, 11
21040 Origgio (Va), Italie

La dernière date à laquelle cette notice a été approuvée est juillet 2019.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Enterogermina® 2 billion/5 ml, oral suspension

Enterogermina® 2 billion, hard capsules

spores of polyantibiotic-resistant *Bacillus clausii* – oral use

<p>Read this leaflet carefully before you start taking this medicine as it contains important information for you.</p> <p>Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.</p> <ul style="list-style-type: none"> Keep this leaflet. You may need to read it again. If you would like more information or advice, ask your doctor or pharmacist. If you experience any of the undesirable effects, including effects not listed in this leaflet, speak to your doctor or pharmacist. See section 4. Talk to your doctor if you do not notice any improvements or if you notice a worsening of symptoms after a brief period of treatment.
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What is in this leaflet:

- What Enterogermina is and what it is used for
- What you need to know before you take Enterogermina
- How to take Enterogermina
- Possible side effects
- How to store Enterogermina
- Further information

1. WHAT ENTEROGERMINA IS AND WHAT IT IS USED FOR

Enterogermina is a medicine consisting of a suspension of 4 strains (S/N, O/C, T, N/R) *Bacillus clausii* spores, normally present in the intestine, without disease-causing capacity (without pathogenic ability).

Enterogermina is used for:

- the prevention and treatment of intestinal disorders related to the alteration in intestinal flora, that manifest themselves as diarrhea, abdominal pain and increase of air in the bowel (intestinal dismicrobism), and vitamin deficiencies in the body resulting from the imbalance of intestinal flora (endogenous avitaminosis);
- coadjutant treatment to restore intestinal microbial flora altered during treatment with antibiotics or chemotherapy;
- the treatment of acute and chronic gastro-intestinal diseases of infants caused by poisoning or alteration of the normal balance of intestinal bacterial flora, that manifest themselves as diarrhea, abdominal pain and increase of air in the bowel (intestinal dismicrobism), or vitamin deficiencies in the organism (avitaminosis).

Health education notes

The intestinal bacterial flora constitutes a real defensive barrier against harmful bacteria. Its balance can be upset by intestinal infections, poisoning, food disorders and changes in diet or use of antibiotics.

Talk to your doctor if you do not notice any improvements or if you notice a worsening of symptoms after a brief period of treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENTEROGERMINA

Contraindications:

Do not take Enterogermina

- if you are allergic to spores of polyantibiotic-resistant *Bacillus clausii* or any of the other ingredients of this medicine (listed in section 6).

Appropriate precautions for use: special warnings:

Warnings and precautions

Talk to your doctor or pharmacist before taking Enterogermina.

This medication is for oral use only. Do not inject or administer through other routes. Improper use of the medicine has resulted in severe anaphylactic reactions such as anaphylactic shock.

During treatment with antibiotics, ingest Enterogermina between one administration and the other of the antibiotic.

If you notice the presence of corpuscles, or of tiny particles in the Enterogermina vials, that does not mean that the product has been impaired, as these are simply clusters of *Bacillus clausii* spores.

Other medicines and Enterogermina

Inform your doctor or your pharmacist if you are taking, have recently taken or could take any other medication, including over-the-counter medication.

No disorders (interactions) are envisaged concerning the association between Enterogermina and other medicines.

Pregnancy and lactation

If you are pregnant, are planning to become pregnant, or are breastfeeding, talk to your doctor or pharmacist before taking this medicine.

Enterogermina may be used during pregnancy and lactation.

Driving and operating machinery

Enterogermina has no or negligible influence on the ability to drive or operate machinery.

3. HOW TO TAKE ENTEROGERMINA

Take this medicine exactly as described in this leaflet or as instructed by your doctor or pharmacist. Check with your doctor or pharmacist if you have any doubts.

Take Enterogermina at regular intervals during the day.

The recommended doses are:

Vials

Adults: 2–3 vials per day.

Breastfeeding infants and children: 1–2 vials per day.

This medication is for oral use only. Do not inject or administer in any other way (see “Warnings and Precautions”).

Shake well before use. To open the vial, unscrew the top part and remove it.



Take the contents as it is or dilute it in water or any other beverage (for example: milk, tea, orange juice).

Once open, take the medicine within a short period of time in order to avoid the alteration of medicine.

Capsules

Adults: 2–3 capsules daily.

Children: 1–2 capsules daily.

Swallow the capsules with a sip of water or other beverages. If you have difficulty swallowing the hard capsules (especially in younger children), use the vials.

Warning: do not exceed the indicated doses without your doctor's advice. Use only for short periods of treatment.

Consult your doctor if the disorder occurs repeatedly or if you have noticed a recent change of any kind in its characteristics.

If you take more Enterogermina than you should

In case of accidental ingestion/administration of an overdose of Enterogermina, immediately notify your doctor or go to the nearest hospital.

If you forget to take Enterogermina

Do not take a double dose to make up for a missed dose.

Proper and regular intake of this medicine promotes a better therapeutic effect.

If you stop taking Enterogermina

No particular effects have been reported, apart from the lack of therapeutic effect.

If you have any doubts regarding the use of this medicine, speak to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

As with all medicines, this medicine can cause undesirable effects, although not everyone is affected.

Unknown frequencies side effects (may affect less than 1 in 10 000 people):

There have been reports of allergic reactions (hypersensitivity), including skin rash, urticaria and angioedema.

In case of reduced body's defence mechanisms and you are taking Enterogermina, *Bacillus clausii* may be found in your blood.

Reporting of side effects

If you get any side effects, talk to your doctor, your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENTEROGERMINA

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the package after "EXP.". The expiry date refers to the last day of that month. The expiry date applies to the product when it is in an intact, properly stored package.

Do not store above 30°C.

Medicinal products should not be thrown out in wastewater or put in household rubbish. Ask your pharmacist how to dispose of medicinal products which you are no longer taking. This will help to protect the environment.

6. FURTHER INFORMATION

What Enterogermina contains

2 billion/5 ml, oral suspension - vials

- The active substance is spores of polyantibiotic-resistant *Bacillus clausii*. Each vial contains 2 billion spores of polyantibiotic-resistant *Bacillus clausii* (strains S/N, O/C, T, N/R).
- The other ingredient is purified water.

2 billion, hard capsules

- The active substance is spores of polyantibiotic-resistant *Bacillus clausii*. Each capsule contains 2 billion spores of polyantibiotic-resistant *Bacillus clausii* (strains S/N, O/C, T, N/R).
- The other ingredients are: heavy kaolin, microcrystalline cellulose, magnesium stearate, gelatine, titanium dioxide (E171), purified water.

What Enterogermina looks like and contents of the pack

2 billion/5 ml, oral suspension - vials

Enterogermina comes in oral suspension form.

Packages containing 10 or 20 5-millilitre vials.

2 billion, hard capsules

Enterogermina comes in the form of hard capsules.

Packages containing 12 or 24 capsules.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

Sanofi S.p.A.
Viale L. Bodio, 37/b
20158 Milano (Italy)

Manufacturer

Sanofi S.p.A.
Viale Europa, 11
21040 Origgio (Va) Italy

This package leaflet was last approved in July 2019.