

## PUBLIC DRUG DATABASE



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Last updated on 03/29/2024

## Fiche info

## Résumé des caractéristiques du produit

## Notice

## SUMMARY

Drug description  
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Use  
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Info. additional

## EFFERALGANMED 300 mg, suppository - Patient leaflet

ANSM - Updated on: 05/08/2022

Name of the medicine

EFFERALGANMED 300 mg, suppository  
Paracetamol

Boxed

**Please read this leaflet carefully before taking this medicine as it contains important information for you.**

You should always take this medicine carefully following the information provided in this leaflet or by your doctor, pharmacist or nurse.

- Keep this notice. You might need to read it again.
- Contact your pharmacist for any advice or information.
- If you experience any side effects, tell your doctor, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. See section 4.
- You should contact your doctor if you do not feel any improvement or if you feel worse after 3 days in case of fever or 5 days in case of pain.

What does this booklet contain ?

1. What is EFFERALGANMED 300 mg, suppository and in what cases is it used?
2. What information should you know before taking EFFERALGANMED 300 mg, suppository?
3. How to take EFFERALGANMED 300 mg, suppository?
4. What are the possible side effects?
5. How to store EFFERALGANMED 300 mg, suppository?
6. Package contents and other information.

**1. WHAT IS EFFERALGANMED 300 mg, suppository AND IN WHAT CASES IS IT USED? ↗**

Pharmacotherapeutic group: OTHER ANALGICS AND ANTIPYRETICS-ANILIDES - ATC code: N02BE01.

This medicine contains paracetamol: an analgesic (it relieves pain) and an antipyretic (it reduces fever).

It is indicated in cases of pain and/or fever such as headaches, flu-like illness, dental pain, aches.

**This presentation is reserved for children weighing 15 to 24 kg (approximately 4 to 9 years) : read the instructions carefully, "Dosage" section.**

For children of different weights, there are other presentations of paracetamol: ask your doctor or pharmacist for advice.

You should contact your doctor if you do not feel any improvement or if you feel worse after 3 days in case of fever or 5 days in case of pain.

**2. WHAT INFORMATION SHOULD YOU KNOW BEFORE TAKING EFFERALGANMED 300 mg, suppository? ↗**

Never take EFFERALGANMED 300 mg, suppository :

- If you are allergic to the active substance or any of the other ingredients contained in this medicine, mentioned in section 6.
- Due to the presence of lecithin derived from soybean oil, this medication is contraindicated in cases of peanut or soy allergy.
- If you have serious liver disease.
- If you have recent anal or rectal inflammation or recent bleeding from the rectum.

IF IN DOUBT, IT IS ESSENTIAL TO SEEK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking EFFERALGANMED 300 mg, suppository.

In case of overdose or taking too high a dose by mistake, consult your doctor immediately.

**This medicine contains paracetamol. Other medications contain it.**

**Check that you are not taking other medicines containing paracetamol, including medicines obtained without a prescription.**

**Do not combine them, so as not to exceed the recommended daily dose.**

**(see section 3 "How to take EFFERALGANMED 300 mg, suppository?").**

With suppositories, there is a risk of local irritation, which is all the more frequent and intense as the duration of treatment is prolonged, the rate of administration is high and the dosage is high.

In case of diarrhea, the suppository form is not suitable.

- If the pain persists for **more than 5 days** or the fever for **more than 3 days**, or in the event of insufficient effectiveness or the occurrence of any other sign, do not continue treatment without consulting your doctor.

Tell your doctor before taking this medicine if any of the following conditions apply to you:

- If you have liver or kidney disease,
- If you have Gilbert's syndrome (non-hemolytic familial jaundice),
- Or in case of alcohol abuse (excessive alcohol consumption (3 or more alcoholic drinks each day)),
- If you suffer from glucose-6-phosphate dehydrogenase (G6PD) deficiency (which may lead to hemolytic anemia),
- If you have nutritional problems (malnutrition (low hepatic glutathione reserves), anorexia, bulimia or cachexia (significant weight loss)),
- If you have problems with dehydration, hypovolemia (significant loss of body water).

If you suffer from acute viral hepatitis or if you discover acute viral hepatitis during your treatment with EFFERALGANMED 300 mg, suppository, talk to your doctor. Your treatment may be suspended by your doctor.

IF IN DOUBT, DO NOT HESITATE TO SEEK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

#### **Children and adolescents**

In a child treated with paracetamol, the combination of another antipyretic is only justified in the event of ineffectiveness. The association should only be established and monitored by a doctor.

#### **Other medicines and EFFERALGANMED 300 mg, suppository**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should contact your doctor if you are taking a medicine that slows clotting (oral anticoagulants). At high doses, EFFERALGANMED 300 mg suppository can increase the action of your anticoagulant. If necessary, your doctor will adjust the dosage of your anticoagulant.

You should contact your doctor if you are taking flucloxacillin (penicillin class antibiotic) because of the increased risk of metabolic acidosis, especially if you have a risk factor for glutathione deficiency such as severe kidney failure, sepsis (serious general infection of the body by pathogenic germs), malnutrition or chronic alcoholism.

Tell your child that your child is taking this medicine if their doctor prescribes a uric acid or blood sugar test.

#### **EFFERALGANMED 300 mg, suppository with food, drinks and alcohol**

Not applicable.

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

For information: If necessary, EFFERALGANMED 300 mg, suppository can be used during pregnancy and breastfeeding. You should use the lowest possible dose that relieves pain and/or fever and take it for the shortest duration possible. Contact your doctor if the pain and/or fever does not improve or if you need to take the medication more frequently.

It is possible that paracetamol can impair women's fertility, reversibly upon stopping treatment.

#### **Driving and using machines**

Paracetamol has no or negligible influence on the ability to drive and use machines.

#### **EFFERALGANMED 300 mg, suppository contains lecithin derived from soybean oil (contained in semi-synthetic glycerides).**

If you are allergic to peanut or soy, do not use this medication.

### **3. HOW TO TAKE EFFERALGANMED 300 mg, suppository? ↗**

Always take this medicine exactly as instructed in this leaflet or as instructed by your doctor, pharmacist or nurse. Check with your doctor, pharmacist or nurse if in doubt.

#### **Dosage**

This presentation is reserved for **children weighing 15 to 24 kg** (approximately 4 to 9 years old).

**The dosage of paracetamol depends on the child's weight; ages are given for information purposes.**

**If you do not know the child's weight, you must weigh them in order to give them the best dose.**

**Paracetamol exists in numerous dosages, allowing treatment to be adapted to the weight of each child.**

The recommended daily dose of paracetamol depends on the child's weight: it is approximately 60 mg/kg/day, divided into 4 doses, or approximately 15 mg/kg every 6 hours.

Due to the risk of rectal irritation, suppository administration should be as short as possible, should not exceed 4 doses per day and will be replaced as soon as possible by oral treatment.

In case of diarrhea, the suppository form is not suitable.

Weight (age)	Dose per administration	Administration interval	Maximum daily dose
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<b>15kg to 24kg</b> (approximately 4 to 9 years old)	300 mg (1 suppository)	6 hours	1200 mg per day (4 suppositories)
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For children, the total dose of paracetamol should not exceed 80 mg/kg/day.

The maximum daily dose should not exceed 60 mg/kg per day in the following situations:

- serious liver damage,
- Gilbert syndrome (non-hemolytic familial jaundice),
- chronic alcoholism,
- chronic malnutrition,
- dehydration.

If you have the impression that the effect of EFFERALGANMED 300 mg, suppository is too strong or too weak, consult your doctor or pharmacist.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

#### **Method and route of administration**

Rectal route.

#### **Frequency of administration**

Systematic intake helps avoid fluctuations in pain or fever.

- In children, they must be regularly spaced, including at night, preferably by 6 hours, and at least 4 hours.

#### **Renal failure**

In the event of kidney disease (renal failure), the minimum interval between 2 doses must be modified by monitoring your kidney function according to the following table:

Creatinine clearance	Administration interval
cl >10 mL/min	6 hours
cl <10 mL/min	8 hours

The total dose of paracetamol should not exceed 60 mg/kg/day.

#### **Duration of treatment**

The duration of treatment is limited:

- 5 days in case of pain,
- 3 days in case of fever.

If the pain persists for more than 5 days or the fever for more than 3 days, or if they worsen, do not continue treatment without consulting your doctor or pharmacist.

**If you take more EFFERALGANMED 300 mg suppository than you should**

**Stop treatment and consult your doctor or medical emergency immediately.**

**An overdose can be fatal.**

In the first 24 hours, the main symptoms of poisoning are: nausea, vomiting, paleness, malaise, sweating, loss of appetite, abdominal pain.

**If you forget to take EFFERALGANMED 300 mg, suppository**

Do not take a double dose to make up for a dose you forgot to take.

**If you stop taking EFFERALGANMED 300 mg, suppository**

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. WHAT ARE THE POSSIBLE SIDE EFFECTS? ↴**

Like all medicines, this medicine can cause side effects, although not everyone gets them.

**Rare side effects : may affect up to 1 in 1,000 people**

- redness of the skin, rash, hives. You must **stop treatment immediately**, notify your doctor and never take medications containing paracetamol again.
- blood spots on the skin (purpura). You must **stop treatment immediately**, notify your doctor and never take medications containing paracetamol again.

**Very rare side effects : may affect up to 1 in 10,000 people**

- serious skin reactions. You must **stop treatment immediately**, notify your doctor and never take medications containing paracetamol again.
- biological changes requiring blood work to be checked: abnormally low levels of certain white blood cells (leukopenia, neutropenia) or certain blood cells such as platelets (thrombocytopenia) which may result in nose or gum bleeding. In this case, consult a doctor.

**Adverse reactions with unknown frequency** : frequency cannot be estimated from the available data

- rash or redness of the skin or allergic reaction which may manifest as sudden swelling of the face and neck which may cause difficulty breathing (angioedema) or sudden discomfort with drop in blood pressure (anaphylactic shock). You must stop treatment immediately, notify your doctor and never take medications containing paracetamol again.
- diarrhea, abdominal pain, abnormal liver function tests.
- with the suppository form, there is a risk of rectal or anal irritation (see Warnings and precautions).

#### **Reporting of side effects**

If you experience any side effects, tell your doctor, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. You can also report adverse effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr).

By reporting side effects, you can help provide more information about the safety of the medicine.

#### **5. HOW TO STORE EFFERALGANMED 300 mg, suppository?** ↗

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. The expiration date refers to the last day of that month.

Store at a temperature not exceeding 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. PACKAGE CONTENTS AND OTHER INFORMATION** ↗

##### **What EFFERALGANMED 300 mg contains, suppository.** ↗

- The active substance is:

Paracetamol..... 300 mg  
For a suppository.

- The other components are:

Semi-synthetic glycerides (including lecithin derived from soybean oil\*). \*See section 2.

##### **What EFFERALGANMED 300 mg, suppository is and contents of the pack** ↗

This medication comes in the form of suppositories.

Box of 10.

##### **Marketing authorization holder** ↗

###### **UPSA SAS**

3, RUE JOSEPH MONIER  
92500 RUEIL-MALMAISON

##### **Marketing authorization operator** ↗

###### **UPSA SAS**

3, RUE JOSEPH MONIER  
92500 RUEIL-MALMAISON

##### **Maker** ↗

###### **UPSA SAS**

304, avenue du Docteur Jean Bru  
47000 agents

Or

###### **UPSA SAS**

979, AVENUE DES PYRENEES  
47520 THE PASSAGE

##### **Names of the medicine in the member states of the European Economic Area** ↗

Not applicable.

##### **The last date this notice was revised is:** ↗

[to be completed later by the holder]

{month YYYY}.

##### **Others** ↗

Detailed information on this medicine is available on the ANSM (France) website.

**Health Education Council:****WHAT TO DO IN CASE OF FEVER:**

Normal body temperature varies from one person to another and is between 36.5°C and 37.5°C. A rise in temperature above 38°C can be considered a fever.

This medicine is intended for children weighing 15 to 24 kg (approximately 4 to 9 years old).

If the problems caused by fever are too bothersome, you can take this medicine which contains paracetamol in accordance with the indicated dosages.

**You can improve the effectiveness of medical treatment by the following measures are :**

- to discover yourself ,
- drink regularly to avoid any risk of dehydration ,
- do not stay in a too hot place .

With this medicine, the fever should go down quickly. Nevertheless :

- if other unusual signs appear,
- if the fever persists for more than 3 days or if it worsens,
- if the headaches become violent, or in the event of vomiting,

**CONSULT YOUR DOCTOR IMMEDIATELY.****WHAT TO DO IN CASE OF PAIN:**

The intensity of pain perception and the ability to resist it varies from person to person.

- If there is no improvement after 5 days of treatment,
- if the pain is violent, unexpected and occurs suddenly (especially severe pain in the chest) and/or on the contrary returns regularly,
- if it is accompanied by other signs such as general malaise, fever, unusual swelling of the painful area, decreased strength in a limb,
- if it wakes you up at night,

**CONSULT YOUR DOCTOR IMMEDIATELY.**

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