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SUMMARY

EFFERALGANMED 300 mg, suppository - Summary of product characteristics

ANSM - Updated on: 05/08/2022

1. NAME OF THE MEDICINAL PRODUCT

EFFERALGANMED 300 mg, suppository

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol .... 300 mg

For a suppository.

Excipient with notable effect: one suppository contains lecithin derived from soybean oil (contained in semi-synthetic glycerides).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suppository.

4. CLINICAL DATA

4.1. Therapeutic indications

Symptomatic treatment of mild to moderate pain and/or febrile conditions.
This presentation is RESERVED **FOR CHILDREN weighing 15 to 24 kg** (approximately 4 to 9 years old).

4.2. Dosage and method of administration

Dosage

Pediatric population

In children, it is imperative to **respect the dosages defined according to the** child's weight and therefore to choose an appropriate presentation. Approximate ages based on weight are given for information only.

The recommended daily dose of paracetamol is approximately 60 mg/kg/day, divided into 4 doses, or approximately 15 mg/kg every 6 hours.
Due to the risk of local toxicity, the administration of a suppository is not recommended more than 4 times per day, and the duration of rectal treatment should be as short as possible.
In case of diarrhea, administration of the suppository is not recommended.

Weight (age)	Dose per administration	Administration interval	**Maximum** daily dose
15kg - 24kg (approximately 4 to 9 years old)	300 mg (1 suppository)	6 hours	1200 mg per day (4 suppositories)

For children, the total dose of paracetamol should not exceed 80 mg/kg/day (see section 4.9).

Maximum recommended doses : see section 4.4.

Renal failure

In the event of renal insufficiency and unless medical advice is given, it is recommended to reduce the dose and increase the minimum interval between two doses according to the following table:

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

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

Hepatic insufficiency

In patients with chronic active or compensated liver disease , particularly those with hepatocellular insufficiency , chronic alcoholism, chronic malnutrition (low hepatic glutathione reserves), Gilbert's syndrome (non-hemolytic familial jaundice) and dehydration , the paracetamol dose should not exceed 60 mg/kg/day.

Special clinical situations

The lowest possible effective daily dose should be considered, without exceeding 60 mg/kg/day under the following conditions:

- mild to moderate hepatocellular insufficiency,
- Gilbert syndrome (non-hemolytic familial jaundice),
- chronic alcoholism,
- chronic malnutrition,
- dehydration.

Administration mode

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.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Due to the presence of lecithin derived from soybean oil, this medication is contraindicated in cases of peanut or soy allergy.

Severe hepatocellular insufficiency or active decompensated liver disease.

Recent history of proctitis, anitis or rectal bleeding.

4.4. Special warnings and precautions for use

Special warnings

To avoid the risk of overdose:

- check the absence of paracetamol in the composition of other medications (medicines obtained with or without a prescription),
- respect the maximum recommended doses.

Maximum recommended doses :

- *in children weighing less than 40 kg* , the total dose of paracetamol should not exceed 80 mg/kg/day (see section 4.9).
- *in children weighing 41 kg to 50 kg* , the total dose of paracetamol should not exceed 3 g per day (see section 4.9).
- *in adults and children over 50 kg* , THE TOTAL DOSE OF PARACETAMOL SHOULD NOT EXCEED 4 GRAMS PER DAY (see section 4.9).

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

Paracetamol can cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed of the early signs of these serious skin reactions, and the appearance of a rash or any other sign of hypersensitivity requires discontinuation of treatment.

Precautions for use

- In a child treated with 60 mg/kg/day of paracetamol, the combination of another antipyretic is only justified in the event of ineffectiveness.
- Paracetamol should be used with caution in cases of:
  - mild to moderate hepatocellular insufficiency,
  - renal failure (see section 4.2),
  - Gilbert syndrome (non-hemolytic familial jaundice),
  - Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency (which can lead to hemolytic anemia),
  - chronic alcoholism, excessive alcohol consumption (3 or more alcoholic drinks each day),
  - anorexia, bulimia or cachexia,
  - chronic malnutrition (low hepatic glutathione reserves),
  - dehydration, hypovolemia (see section 4.2).

If acute viral hepatitis is discovered, treatment should be stopped.

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

4.5. Interactions with other drugs and other forms of interactions

Associations subject to precautions for use

+ Vitamin K antagonists

Risk of increased effect of the vitamin K antagonist and the risk of bleeding when taking paracetamol at maximum doses (4 g/day) for at least 4 days.

More frequent monitoring of INR. Possible adaptation of the dosage of the vitamin K antagonist during treatment with paracetamol and after its cessation.

+ Flucloxacillin

Caution is advised when acetaminophen is administered concomitantly with flucloxacillin due to the increased risk of high anion gap metabolic acidosis (EMTAE), particularly in patients with a risk factor for glutathione deficiency such as severe renal failure, sepsis, malnutrition or chronic alcoholism. Close monitoring is recommended to detect the appearance of AMTAE, by testing for urinary 5-oxoproline.

Interactions with paraclinical examinations

Taking paracetamol can distort the measurement of blood sugar by the glucose oxidase-peroxidase method in the event of abnormally high concentrations.

Taking paracetamol can distort blood uric acid measurements using the phosphotungstic acid method.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

Studies carried out in animals have not demonstrated any teratogenic or foetotoxic effect of paracetamol.

A vast amount of data from pregnant women demonstrates the absence of any malformation or fetal/neonatal toxicity. Epidemiological studies devoted to the neurodevelopment of children exposed to paracetamol in utero produce inconclusive results. If clinically necessary, paracetamol can be used during pregnancy; however, it should be used at the lowest effective dose, for the shortest possible duration and with the lowest possible frequency.

Feeding with milk

Paracetamol is excreted in small amounts in breast milk following oral administration. Cases of skin rash have been reported in breast-fed infants.

In therapeutic doses, administration of this drug is possible during breastfeeding.

Fertility

Not applicable.

4.7. Effects on the ability to drive and use machines

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

4.8. Side effects

RELATED TO PARACETAMOL

- A few rare cases of hypersensitivity reactions such as anaphylactic shock, hypotension (as a symptom of anaphylaxis), angioedema, erythema, urticaria, skin rash, purpura have been reported. Their occurrence requires permanent discontinuation of this medication and related medications.
- Very rare cases of serious skin reactions (acute generalized exanthematous pustulosis, toxic epidermal necrolysis and Stevens-Johnson syndrome) have been reported and require discontinuation of treatment.
- Very exceptional cases of thrombocytopenia, leukopenia and neutropenia have been reported.
- Cases of diarrhea, abdominal pain, increased liver enzymes, increased or decreased INR have been reported.

RELATED TO PHARMACEUTICAL FORM

- Rectal and anal irritation.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continuous monitoring of the benefit/risk ratio of the drug. Healthcare professionals report any suspected adverse reactions 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 .

4.9. Overdose

The risk of serious poisoning may be particularly high in the elderly, in young children, in patients with liver damage, in cases of chronic alcoholism, in patients suffering from chronic malnutrition and in patients receiving inducers. enzymatic. In these cases, poisoning can be fatal.

Symptoms

Nausea, vomiting, anorexia, pallor, malaise, sweating, abdominal pain generally appear within the first 24 hours.

An overdose, from 10 g of paracetamol in a single dose in adults and 150 mg/kg of body weight in a single dose in children, causes hepatic cytolysis likely to lead to complete and irreversible necrosis. resulting in hepatocellular insufficiency, metabolic acidosis, encephalopathy which can lead to coma and death.

Simultaneously, there is an increase in hepatic transaminases, lactate dehydrogenase, bilirubin and a decrease in prothrombin levels which may appear 12 to 48 hours after ingestion. Clinical symptoms of liver damage are generally observed after 1 to 2 days, and reach a maximum after 3 to 4 days.

Overdose can also lead to acute pancreatitis and hyperamylasemia.

Emergency driving

- Stop treatment.
- Immediate transfer to hospital.
- Take a tube of blood to make the initial plasma dosage of paracetamol as soon as possible from the 4th hour after ingestion.
- Rapid evacuation of the ingested product, by gastric lavage.
- Treatment of overdose classically includes administration as early as possible of the antidote N-acetylcysteine by IV or oral route if possible before the tenth hour.
- Symptomatic treatment.
- Liver tests should be performed at the start of treatment and repeated every 24 hours. In most cases, liver transaminases return to normal within 1 to 2 weeks with full recovery of liver function. However, in very severe cases, a liver transplant may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: OTHER ANALGESICS AND ANTIPYRETICS-ANILIDES , ATC code: N02BE01.
(N: Central nervous system).

Action mechanism

Paracetamol has a central and peripheral mechanism of action.

5.2. Pharmacokinetic properties

Absorption

Rectally, the absorption of paracetamol is slower than orally.

However, it is total. Maximum plasma concentrations are reached 2 to 3 hours after administration.

Distribution

Paracetamol distributes quickly to all tissues. Concentrations are comparable in blood, saliva and plasma. Plasma protein binding is low.

Biotransformation

Paracetamol is metabolized mainly in the liver. The 2 major metabolic pathways are glucuronidation and sulfoconjugation. This last pathway is quickly saturable at doses higher than therapeutic doses. A minor pathway, catalyzed by cytochrome P 450, is the formation of a reactive intermediate (N-acetyl benzoquinone imine), which, under normal conditions of use, is rapidly detoxified by reduced glutathione and eliminated in the urine. after conjugation to cysteine and mercaptopuric acid. On the other hand, during massive poisonings, the quantity of this toxic metabolite is increased.

Elimination

Elimination is mainly urinary. 90% of the administered dose is eliminated by the kidney within 24 hours, mainly in glucuronide (60 to 80%) and sulfoconjugate (20 to 30%) form. Less than 5% is eliminated unchanged.

The elimination half-life is 4 to 5 hours.

Pathophysiological variations

Renal insufficiency : in case of renal insufficiency (see section 4.2), the elimination of paracetamol and its metabolites is delayed.

5.3. Preclinical safety data

No conventional studies using currently accepted standards to assess reproductive and developmental toxicity are available.

Conventional preclinical studies of safety pharmacology, genotoxicity, repeated dose toxicity and carcinogenicity have not shown any particular risk to humans at therapeutic doses.

At hepatotoxic doses, paracetamol demonstrated genotoxic and carcinogenic potential (liver and bladder tumors) in mice and rats. However, this genotoxic and carcinogenic activity is considered to be related to changes in the metabolism of paracetamol upon administration of high doses or concentrations and does not pose a risk for clinical use.

In rats, effects on male fertility (oligospermia, abnormal sperm motility and reduced fertilizing potential of sperm) at high doses (500 and 1000 mg/kg body weight per day) were observed.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Semi-synthetic glycerides (including lecithin derived from soybean oil).

6.2. Incompatibilities

Not applicable.

6.3. The duration of the conversation

3 years.

6.4. Special storage precautions

Store at a temperature not exceeding 30°C.

6.5. Nature and contents of outer packaging

10 suppositories in blister pack (PVC/PE).

6.6. Special precautions for disposal and handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

UPSA SAS
3, RUE JOSEPH MONIER
92500 RUEIL-MALMAISON

[Tel, fax, e-Mail: to be completed later by the holder]

8. MARKETING AUTHORIZATION NUMBER(S)

- 339 058-5 or 34009 339 058 5 9: 10 suppositories in blister pack (PVC/PE).

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

[to be completed later by the holder]
Date of first authorization: {DD month YYYY}
Last renewal date: {DD month YYYY}

10. TEXT UPDATED DATE

[to be completed later by the holder]
{DD month YYYY}

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.

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