PACKAGE LEAFLET: INFORMATION FOR THE USER

hameln

Flumazenil 100 micrograms/ml solution for injection/infusion

flumazenil

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Flumazenil is and what it is used for
2. What you need to know before you are given Flumazenil
3. How Flumazenil is given
4. Possible side effects
5. How to store Flumazenil
6. Contents of the pack and other information

1. WHAT FLUMAZENIL IS AND WHAT IT IS USED FOR

Flumazenil is a counteragent (antidote) for the complete or partial reversal of the central sedative effects of benzodiazepines (specific group with sedative, sleep inducing, muscle relaxing and anxiolytic properties).

It may therefore be used in anaesthesia to wake you up after certain diagnostic tests or in intensive care if you have been held under sedative conditions. Flumazenil may also be used for the diagnosis and treatment of intoxications or overdose with benzodiazepines.

Flumazenil may also be used in children (older than 1 year) to wake them up after they have been held under sedative conditions with benzodiazepines.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN FLUMAZENIL

Flumazenil will be given to you by a specially trained doctor under strict supervision.

You must NOT be given Flumazenil if you are:
- **allergic** (hypersensitive) to Flumazenil or any of the other ingredients of this medicine (listed in section 6).
- taking benzodiazepines to control a life-threatening condition such as an increase in brain pressure (raised intracranial pressure) or a serious epileptic seizure (status epilepticus).

Warnings and precautions

Before you receive Flumazenil, tell your doctor if you:
- have epilepsy and have taken benzodiazepines for a long period. Flumazenil can cause seizures.
- have liver problems.
- have or in the past have had a serious head injury Flumazenil can cause increased pressure in your brain.
- were anxious before an operation or had an anxious seizure or have long term anxiety.
- had panic attacks in the past. Flumazenil can cause new attacks.
- had long-term or high dosage treatment of benzodiazepines. A rapid injection of Flumazenil at a dose higher than 1000 micrograms can cause withdrawal symptoms.
- have a history of alcoholism or other substance abuse you have a higher risk of benzodiazepine tolerance and dependence and therefore a higher risk of withdrawal symptoms. Your anaesthetist will adjust your dose carefully.

Beware also the following

Flumazenil only reverses the effects of benzodiazepines.
- o if lowering of consciousness or sedation is caused by another agent, it is unlikely that Flumazenil will counteract it.
- o although Flumazenil is given to reverse drowsiness, you may experience a return of drowsiness for up to 24 hours after Flumazenil is given. This is because the sedative effects of benzodiazepines lasts longer than the anti-sedative effects of Flumazenil. Therefore you will be monitored, if possible in intensive care, until all possible effects of the benzodiazepine have worn off.
- o if you undergo an operation that is particularly invasive and causes a lot of pain, the anaesthetist may keep you in a sedated condition.
- o Flumazenil is not recommended to treat benzodiazepine addiction or the symptoms of it.

If Flumazenil is administered to you at the end of your operation to wake you up, it should not be given until the effects of muscle relaxants have gone away.

Children

In children previously sedated with midazolam: These children should be closely observed in intensive care units for at least 2 hours after administration of Flumazenil because repeated sedation or difficulty with breathing can occur. In case of sedation by other benzodiazepines, the monitoring must be adjusted according to their expected duration.

Children should only receive Flumazenil after deliberate sedation. There are insufficient data for any other indications. The same applies for children below the age of 1 year

Other medicines and Flumazenil

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This information is needed so that your anaesthetist can adjust your dose carefully.

In particular please tell your doctor or nurse if you are taking any of the following medicines:
- zopiclone and triazolopyridazine (used to treat insomnia)
- benzodiazepines (e.g. diazepam, midazolam)
- tricyclic or tetracyclic antidepressants like amitriptyline, nortriptyline, clomipramine, mirtazapine, mianserin and imipramine

When using Flumazenil in cases of an accidental overdose it has to be taken into account that the toxic effects of other psychotropic medicinal products (especially tricyclic antidepressants like Imipramine) taken concurrently, may increase with the subsidence of the benzodiazepine effect.

Pregnancy and breast-feeding

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 you are given this medicine.

The risk to the unborn foetus in humans has not been determined, therefore, Flumazenil is not recommended for use during pregnancy, unless the benefits to the patient clearly outweigh the risks to the unborn foetus, such as in a life-threatening, emergency situation.

It is not known whether Flumazenil is excreted in breast milk. Therefore it is better not to breast-feed for 24 hours after Flumazenil has been given.

Driving and using machines

The effect of Flumazenil is shorter than the effect of benzodiazepines and so it is possible that you may feel sleepy again. Do not drive motor vehicles and do not operate any tools or machines for a period of 24 hours after the administration of Flumazenil.

Flumazenil contains sodium

This medicinal product contains 3.7 mg sodium (main component of cooking/table salt) per ml.
- Each 5 mL ampoule of the product contains less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.
- Each 10 mL ampoule of the product contains 37 mg sodium. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW FLUMAZENIL IS GIVEN

Flumazenil is administered in the vein (intravenously) either diluted or undiluted. Flumazenil will be given to you under strict supervision of a doctor with experience in anaesthesia. The doctor will determine how much Flumazenil to give. This depends on your age, weight, how well your liver and kidneys are working and what you need the medicine for. Flumazenil can be used in combination with other agents, which are used to return somebody to consciousness.

Adults

The dosage depends on the situation; usually, an initial dose of 200 micrograms is administered into your vein over 15 seconds. If your state of consciousness does not improve sufficiently after 60 seconds, another dose of 100 micrograms can be administered. This can repeated after 60 seconds until you reach a sufficient state of consciousness. The maximum dose that can be administered is 1000 micrograms after anaesthesia and 2000 micrograms in intensive care.

The treatment is discontinued every 6 hours in order to determine if sedation re-occurs.

Children older than 1 year

Usually, an initial dose of 10 micrograms per kilogram body weight (up to 200 micrograms) is administered into a vein over 15 seconds. If the state of consciousness does not improve sufficiently after 45 seconds, another dose of 10 micrograms per kilogram body weight (up to 200 micrograms) can be administered. This can be repeated after 60 seconds up to four times to a maximum total dose of 50 micrograms per kilogram body weight or 1000 micrograms, whichever is lower.

The following information is intended for medical or healthcare professionals only:

hameln

PREPARATION GUIDE FOR:

Flumazenil 100 micrograms/ml solution for injection/infusion

Please refer to Summary of Product Characteristics for full prescribing and other information.

1. Incompatibilities

This medicinal product must not be mixed with other medicinal products except for following:

Sodium chloride 9 mg/ml (0.9%) solution, dextrose 50 mg/ml (5%) solution or sodium chloride 4.5 mg/ml (0.45%) + dextrose 25 mg/ml (2.5%) solution (10, 20, 50 ml Flumazenil 100 micrograms/ml in 500 ml solution). Compatibility between flumazenil and other solutions for injection has not been established.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

2. Posology and method of administration

This medicinal product is for single use only and any unused solution should be discarded.

When flumazenil is to be used in infusion, it must be diluted prior to infusion.

Posology

Adults

Anaesthesia

The recommended starting dose is 200 micrograms administered intravenously over 15 seconds. If the required level of consciousness is not obtained within 60 seconds, a further dose of 100 micrograms can be injected and repeated at 60-second intervals, up to a maximum dose of 1000 micrograms. The usual dose is 300 to 600 micrograms, but may deviate depending on the patient's characteristics and the benzodiazepine used.

Intensive Care

The recommended starting dose is 300 micrograms administered intravenously. If the required level of consciousness is not obtained within 60 seconds, a further dose of 100 micrograms can be injected and repeated at 60-second intervals, up to a total dose of 2000 micrograms or until the patient awakes.

If drowsiness recurs, a second bolus injection of flumazenil may be administered. An intravenous infusion of 100 - 400 micrograms/hour may be useful.

There is little information about the use of Flumazenil in children under 1 year of age. Your doctor will decide if it is necessary to give Flumazenil to your child of this age.

Elderly
Elderly people are generally more sensitive to the effects of Flumazenil and should be treated with due caution.

Patients with liver impairment
If you have liver problems your doctor may give you a reduced dose.

If you have any further questions on how this product will be given, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flumazenil can cause side effects, although not everybody gets them. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you experience any of the following tell the doctor or nurse immediately. Flumazenil may cause allergic reactions. Symptoms of allergic reactions include, swelling of the face, lips throat or tongue, rash and difficulty breathing.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):
- nausea

Common (may affect up to 1 in 10 people):
- allergic reactions
- strong emotional lability
- having problems in initiating and maintaining sleep (insomnia)
- feeling sleepy (somnolence)
- dizziness
- headache
- involuntary trembling or quivering (tremor)
- dry mouth
- hyperventilation
- speech disorder
- individual cutaneous sensations (e.g. cold, warmth, tingling, pressure, etc.) in the absence of stimulation (paraesthesia)
- double vision
- strabismus (a condition in which the eyes are not properly aligned with each other)
- increase in lacrimation
- reddening of the skin
- low blood pressure on transition from lying to standing
- transient increased blood pressure
- vomiting
- hiccup
- sweating
- pain at the injection site

Common after rapid injection (not requiring treatment):
- anxiety
- agitation
- heart palpitations

Uncommon (may affect up to 1 in 100 people):
- fear
- convulsions
- abnormal hearing
- slow or rapid heart action
- premature beat of your heart (extrasystole)
- difficulty in breathing
- cough
- nasal congestion
- chest pain
- shivering

Rare (may affect up to 1 in 1,000 people):
- severe allergic reactions

If you have been treated with high doses of benzodiazepines or for long periods Flumazenil can induce withdrawal symptoms such as tension, agitation, anxiety, strong emotional lability, confusion, hallucinations, dizziness, sweating, rapid heart action, tremor and convulsions, panic attacks, abnormal crying, agitation and aggressive behaviour.

Additional side effects in children
In general the undesirable effects in children do not differ much from that in adults. When using Flumazenil to awake a child from sedation, abnormal crying, agitation and aggressive behaviour have been reported.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUMAZENIL

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Do not freeze. Keep the ampoules in the outer carton in order to protect from light.
- After opening, the solution has to be used immediately.
- Any unused solution from opened ampoules should be discarded.
- Do not use this medicine if you notice that the solution is not clear and colourless.
- Do not use Flumazenil after the expiry date which is stated on the packaging after "EXP:" The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Shelf-life after dilution:
  Chemical and physical in-use stability of the dilutions has been demonstrated for 24 hours at 25°C. From the microbiological point of view, the dilutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flumazenil contains
The **active substance** is flumazenil.

1 ml solution for injection/infusion contains 100 micrograms flumazenil.

1 ampoule with 5 ml solution contains 500 micrograms flumazenil.

1 ampoule with 10 ml solution contains 1000 micrograms flumazenil.

The **other ingredients** are disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide and water for injections.

What Flumazenil looks like and contents of the pack
Flumazenil is a clear and colourless solution in glass ampoules.

Boxes of 5 or 10 ampoules with 5 ml.

Boxes of 5 or 10 ampoules with 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
hameln pharma ltd

Nexus, Gloucester Business Park

Gloucester, GL3 4AG, United Kingdom

Marketing Authorisation Number
PL 01502/0128

Manufacturer
Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln
Germany

hameln rds s.r.o.
Horná 36
90001 Modra
Slovak Republic

This medicinal product is authorised in the Member States of the EEA under the following names:

DE	Flumazenil-hameln 0,1 mg/ml Injektions-/ Infusionslösung
DK	Flumazenil hameln
FI	Flumazenil hameln 0,1 mg/ml injektio-/ infuusioneste, liuos
IT	Flumazenil hameln 0,1 mg/ml soluzione iniettabile o per infusione
NL	Flumazenil hameln 0,1 mg/ml, oplossing voor injectie / infusie
NO	Flumazenil hameln 0,1 mg/ml injeksjons-/ infusjonsvæske, oppløsning
SE	Flumazenil hameln

This leaflet was last revised in August 2025.

45847/42/25

The dosage and rate of infusion should be adjusted individually to achieve the desired level of consciousness.

If a significant improvement in consciousness or respiratory function is not obtained after repeated doses of flumazenil, a non-benzodiazepine aetiology must be assumed.

Infusion should be discontinued every 6 hours to verify whether re-sedation occurs.

To avoid withdrawal symptoms in patients treated for a long period of time with high doses of benzodiazepines in the intensive care unit, the dosage of flumazenil has to be titrated individually and the injection has to be administered slowly.

Special Populations

Elderly

In the absence of data on the use of flumazenil in elderly patients, it should be noted that this population is generally more sensitive to the effects of medicinal products and should be treated with due caution.

Patients with renal or hepatic impairment

Since flumazenil is primarily metabolised in the liver, careful titration of dosage is recommended in patients with impaired hepatic function. No dosage adjustments are required in patients with renal impairment.

Paediatric population

Children above 1 year of age

For the reversal of conscious sedation induced with benzodiazepines in children above 1 year of age, the recommended initial dose is 10 micrograms/kg (up to 200 micrograms), administered intravenously over 15 seconds. If the desired level of consciousness is not obtained after waiting an additional 45 seconds, further injection of 10 micrograms/kg may be administered (up to 200 micrograms) and repeated at 60 second intervals where necessary (a maximum of 4 times) to a maximum total dose of 50 micrograms/kg or 1000 micrograms, whichever is lower. The dose should be individualised to the patient's response. No data are available on the safety and efficacy of repeated administration of flumazenil to children for re-sedation.

Children under the age of 1 year

There are insufficient data on the use of flumazenil in children younger than 1 year.

Therefore flumazenil should only be administered in children younger than 1 year if the potential benefits to the patient outweigh the possible risk.

Method of administration

Flumazenil must be administered intravenously by an anesthetist or a doctor with experience in anesthesiology.

Flumazenil may be administered as an infusion – for instructions on dilution of the medicinal product before administration, see section 1.

Flumazenil may be used concomitantly with other resuscitative measures.

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It may therefore be used in anaesthesia to wake you up after certain diagnostic tests or in intensive care if you have been held under sedative conditions. Flumazenil may also be used for the diagnosis and treatment of intoxications or overdose with benzodiazepines.

Flumazenil may also be used in children (older than 1 year) to wake them up after they have been held under sedative conditions with benzodiazepines.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN FLUMAZENIL

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You must NOT be given Flumazenil if you are:
- **allergic** (hypersensitive) to Flumazenil or any of the other ingredients of this medicine (listed in section 6).
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Warnings and precautions

Before you receive Flumazenil, tell your doctor if you:
- have epilepsy and have taken benzodiazepines for a long period. Flumazenil can cause seizures.
- have liver problems.
- have or in the past have had a serious head injury Flumazenil can cause increased pressure in your brain.
- were anxious before an operation or had an anxious seizure or have long term anxiety.
- had panic attacks in the past. Flumazenil can cause new attacks.
- had long-term or high dosage treatment of benzodiazepines. A rapid injection of Flumazenil at a dose higher than 1000 micrograms can cause withdrawal symptoms.
- have a history of alcoholism or other substance abuse you have a higher risk of benzodiazepine tolerance and dependence and therefore a higher risk of withdrawal symptoms. Your anaesthetist will adjust your dose carefully.

Beware also the following

Flumazenil only reverses the effects of benzodiazepines.
- o if lowering of consciousness or sedation is caused by another agent, it is unlikely that Flumazenil will counteract it.
- o although Flumazenil is given to reverse drowsiness, you may experience a return of drowsiness for up to 24 hours after Flumazenil is given. This is because the sedative effects of benzodiazepines lasts longer than the anti-sedative effects of Flumazenil. Therefore you will be monitored, if possible in intensive care, until all possible effects of the benzodiazepine have worn off.
- o if you undergo an operation that is particularly invasive and causes a lot of pain, the anaesthetist may keep you in a sedated condition.
- o Flumazenil is not recommended to treat benzodiazepine addiction or the symptoms of it.

If Flumazenil is administered to you at the end of your operation to wake you up, it should not be given until the effects of muscle relaxants have gone away.

Children

In children previously sedated with midazolam: These children should be closely observed in intensive care units for at least 2 hours after administration of Flumazenil because repeated sedation or difficulty with breathing can occur. In case of sedation by other benzodiazepines, the monitoring must be adjusted according to their expected duration.

Children should only receive Flumazenil after deliberate sedation. There are insufficient data for any other indications. The same applies for children below the age of 1 year

Other medicines and Flumazenil

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This information is needed so that your anaesthetist can adjust your dose carefully.

In particular please tell your doctor or nurse if you are taking any of the following medicines:
- zopiclone and triazolopyridazine (used to treat insomnia)
- benzodiazepines (e.g. diazepam, midazolam)
- tricyclic or tetracyclic antidepressants like amitriptyline, nortriptyline, clomipramine, mirtazapine, mianserin and imipramine

When using Flumazenil in cases of an accidental overdose it has to be taken into account that the toxic effects of other psychotropic medicinal products (especially tricyclic antidepressants like Imipramine) taken concurrently, may increase with the subsidence of the benzodiazepine effect.

Pregnancy and breast-feeding

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 you are given this medicine.

The risk to the unborn foetus in humans has not been determined, therefore, Flumazenil is not recommended for use during pregnancy, unless the benefits to the patient clearly outweigh the risks to the unborn foetus, such as in a life-threatening, emergency situation.

It is not known whether Flumazenil is excreted in breast milk. Therefore it is better not to breast-feed for 24 hours after Flumazenil has been given.

Driving and using machines

The effect of Flumazenil is shorter than the effect of benzodiazepines and so it is possible that you may feel sleepy again. Do not drive motor vehicles and do not operate any tools or machines for a period of 24 hours after the administration of Flumazenil.

Flumazenil contains sodium

This medicinal product contains 3.7 mg sodium (main component of cooking/table salt) per ml.
- Each 5 mL ampoule of the product contains less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.
- Each 10 mL ampoule of the product contains 37 mg sodium. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW FLUMAZENIL IS GIVEN

Flumazenil is administered in the vein (intravenously) either diluted or undiluted. Flumazenil will be given to you under strict supervision of a doctor with experience in anaesthesia. The doctor will determine how much Flumazenil to give. This depends on your age, weight, how well your liver and kidneys are working and what you need the medicine for. Flumazenil can be used in combination with other agents, which are used to return somebody to consciousness.

Adults

The dosage depends on the situation; usually, an initial dose of 200 micrograms is administered into your vein over 15 seconds. If your state of consciousness does not improve sufficiently after 60 seconds, another dose of 100 micrograms can be administered. This can repeated after 60 seconds until you reach a sufficient state of consciousness. The maximum dose that can be administered is 1000 micrograms after anaesthesia and 2000 micrograms in intensive care.

The treatment is discontinued every 6 hours in order to determine if sedation re-occurs.

Children older than 1 year

Usually, an initial dose of 10 micrograms per kilogram body weight (up to 200 micrograms) is administered into a vein over 15 seconds. If the state of consciousness does not improve sufficiently after 45 seconds, another dose of 10 micrograms per kilogram body weight (up to 200 micrograms) can be administered. This can be repeated after 60 seconds up to four times to a maximum total dose of 50 micrograms per kilogram body weight or 1000 micrograms, whichever is lower.

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The following information is intended for medical or healthcare professionals only:

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PREPARATION GUIDE FOR:

Flumazenil 100 micrograms/ml solution for injection/infusion

Please refer to Summary of Product Characteristics for full prescribing and other information.

1. Incompatibilities

This medicinal product must not be mixed with other medicinal products except for following:

Sodium chloride 9 mg/ml (0.9%) solution, dextrose 50 mg/ml (5%) solution or sodium chloride 4.5 mg/ml (0.45%) + dextrose 25 mg/ml (2.5%) solution (10, 20, 50 ml Flumazenil 100 micrograms/ml in 500 ml solution). Compatibility between flumazenil and other solutions for injection has not been established.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

2. Posology and method of administration

This medicinal product is for single use only and any unused solution should be discarded.

When flumazenil is to be used in infusion, it must be diluted prior to infusion.

Posology

Adults

Anaesthesia

The recommended starting dose is 200 micrograms administered intravenously over 15 seconds. If the required level of consciousness is not obtained within 60 seconds, a further dose of 100 micrograms can be injected and repeated at 60-second intervals, up to a maximum dose of 1000 micrograms. The usual dose is 300 to 600 micrograms, but may deviate depending on the patient's characteristics and the benzodiazepine used.

Intensive Care

The recommended starting dose is 300 micrograms administered intravenously. If the required level of consciousness is not obtained within 60 seconds, a further dose of 100 micrograms can be injected and repeated at 60-second intervals, up to a total dose of 2000 micrograms or until the patient awakes.

There is little information about the use of Flumazenil in children under 1 year of age. Your doctor will decide if it is necessary to give Flumazenil to your child of this age.

Elderly

Elderly people are generally more sensitive to the effects of Flumazenil and should be treated with due caution.

Patients with liver impairment

If you have liver problems your doctor may give you a reduced dose.

If you have any further questions on how this product will be given, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flumazenil can cause side effects, although not everybody gets them. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you experience any of the following tell the doctor or nurse immediately. Flumazenil may cause allergic reactions. Symptoms of allergic reactions include, swelling of the face, lips throat or tongue, rash and difficulty breathing.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- nausea

Common (may affect up to 1 in 10 people):

- allergic reactions
- strong emotional lability
- having problems in initiating and maintaining sleep (insomnia)
- feeling sleepy (somnolence)
- dizziness
- headache
- involuntary trembling or quivering (tremor)
- dry mouth
- hyperventilation
- speech disorder
- individual cutaneous sensations (e.g. cold, warmth, tingling, pressure, etc.) in the absence of stimulation (paraesthesia)
- double vision
- strabismus (a condition in which the eyes are not properly aligned with each other)
- increase in lacrimation
- reddening of the skin
- low blood pressure on transition from lying to standing
- transient increased blood pressure
- vomiting
- hiccup
- sweating
- pain at the injection site

Common after rapid injection (not requiring treatment):

- anxiety
- agitation
- heart palpitations

Uncommon (may affect up to 1 in 100 people):

- fear
- convulsions
- abnormal hearing
- slow or rapid heart action
- premature beat of your heart (extrasystole)
- difficulty in breathing
- cough
- nasal congestion
- chest pain
- shivering

Rare (may affect up to 1 in 1,000 people):

- severe allergic reactions

If you have been treated with high doses of benzodiazepines or for long periods Flumazenil can induce withdrawal symptoms such as tension, agitation, anxiety, strong emotional lability, confusion, hallucinations, dizziness, sweating, rapid heart action, tremor and convulsions, panic attacks, abnormal crying, agitation and aggressive behaviour.

Additional side effects in children

In general the undesirable effects in children do not differ much from that in adults. When using Flumazenil to awake a child from sedation, abnormal crying, agitation and aggressive behaviour have been reported.

Reporting of side effects

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5. HOW TO STORE FLUMAZENIL

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Do not freeze. Keep the ampoules in the outer carton in order to protect from light.
- After opening, the solution has to be used immediately.
- Any unused solution from opened ampoules should be discarded.
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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flumazenil contains

The **active substance** is flumazenil.

1 ml solution for injection/infusion contains 100 micrograms flumazenil.

1 ampoule with 5 ml solution contains 500 micrograms flumazenil.

1 ampoule with 10 ml solution contains 1000 micrograms flumazenil.

The **other ingredients** are disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide and water for injections.

What Flumazenil looks like and contents of the pack

Flumazenil is a clear and colourless solution in glass ampoules.

Boxes of 5 or 10 ampoules with 5 ml.

Boxes of 5 or 10 ampoules with 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

hameln pharma ltd

Nexus, Gloucester Business Park

Gloucester, GL3 4AG, United Kingdom

Marketing Authorisation Number

PL 01502/0128

Manufacturer

Siegfried Hameln GmbH
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hameln rds s.r.o.
Horná 36
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This medicinal product is authorised in the Member States of the EEA under the following names:

DE	Flumazenil-hameln 0,1 mg/ml Injektions-/Infusionslösung
DK	Flumazenil hameln
FI	Flumazenil hameln 0,1 mg/ml injektio-/infuusioneste, liuos
IT	Flumazenil hameln 0,1 mg/ml soluzione iniettabile o per infusione
NL	Flumazenil hameln 0,1 mg/ml, oplossing voor injectie / infusie
NO	Flumazenil hameln 0,1 mg/ml injeksjons-/infusjonsvæske, oppløsning
SE	Flumazenil hameln

This leaflet was last revised in August 2025.

119/42/25

If drowsiness recurs, a second bolus injection of flumazenil may be administered. An intravenous infusion of 100 - 400 micrograms/hour may be useful.

The dosage and rate of infusion should be adjusted individually to achieve the desired level of consciousness.

If a significant improvement in consciousness or respiratory function is not obtained after repeated doses of flumazenil, a non-benzodiazepine aetiology must be assumed.

Infusion should be discontinued every 6 hours to verify whether re-sedation occurs.

To avoid withdrawal symptoms in patients treated for a long period of time with high doses of benzodiazepines in the intensive care unit, the dosage of flumazenil has to be titrated individually and the injection has to be administered slowly.

Special Populations

Elderly

In the absence of data on the use of flumazenil in elderly patients, it should be noted that this population is generally more sensitive to the effects of medicinal products and should be treated with due caution.

Patients with renal or hepatic impairment

Since flumazenil is primarily metabolised in the liver, careful titration of dosage is recommended in patients with impaired hepatic function. No dosage adjustments are required in patients with renal impairment.

Paediatric population

Children above 1 year of age

For the reversal of conscious sedation induced with benzodiazepines in children above 1 year of age, the recommended initial dose is 10 micrograms/kg (up to 200 micrograms), administered intravenously over 15 seconds. If the desired level of consciousness is not obtained after waiting an additional 45 seconds, further injection of 10 micrograms/kg may be administered (up to 200 micrograms) and repeated at 60 second intervals where necessary (a maximum of 4 times) to a maximum total dose of 50 micrograms/kg or 1000 micrograms, whichever is lower. The dose should be individualised to the patient's response. No data are available on the safety and efficacy of repeated administration of flumazenil to children for re-sedation.

Children under the age of 1 year

There are insufficient data on the use of flumazenil in children younger than 1 year.

Therefore flumazenil should only be administered in children younger than 1 year if the potential benefits to the patient outweigh the possible risk.

Method of administration

Flumazenil must be administered intravenously by an anesthetist or a doctor with experience in anesthesiology.

Flumazenil may be administered as an infusion – for instructions on dilution of the medicinal product before administration, see section 1.

Flumazenil may be used concomitantly with other resuscitative measures.