PACKAGE LEAFLET
Size: 180 x 290 mm (Front Back)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Desmopressin acetate 100 micrograms and 200 micrograms tablets

Read all of this leaflet carefully before you start taking 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 desmopressin acetate tablets are and what they are used for
2. What you need to know before you take desmopressin acetate tablets
3. How to take desmopressin acetate tablets
4. Possible side effects
5. How to store desmopressin acetate tablets
6. Contents of the pack and other information

1. WHAT DESMOPRESSIN ACETATE TABLETS ARE AND WHAT THEY ARE USED FOR

The ingredient that makes the tablet work (the active substance) is called desmopressin acetate. Desmopressin is an antidiuretic, which reduces the amount of urine produced by the kidneys.
Desmopressin acetate tablets are used to treat:
- Primary nocturnal enuresis (bedwetting) in children (from 5 years of age) and adults (up to 65 years of age)
- Cranial diabetes insipidus (a condition that causes extreme thirst and the continuous production of large volumes of dilute urine)
  IMPORTANT: This should not be confused with diabetes mellitus (sugar diabetes)
- Post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DESMOPRESSIN ACETATETABLETS

Do not take desmopressin acetate tablets if you:
- are **allergic** to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- **have a serious heart of kidney disease**
- **are taking diuretics (water tablets)**
- **drink** unusually **large amounts** of fluids including alcohol
- are being treated for bedwetting and are under 5 years old or over 65 years old
- are being treated for bedwetting and have high or low blood pressure
- know you have a low level of sodium in your blood (hyponatraemia)
- suffer from "syndrome of inappropriate high secretion of antidiuretic hormone" (SIADH)

Warnings and precautions:
Talk to your doctor, pharmacist or nurse before taking desmopressin acetate tablets:
- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, systemic infections, fever, gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance
- if you have cystic fibrosis

Other medicines and Desmopressin acetate tablets
Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:
- **tricyclic or SSRI antidepressants** (used to treat depression)
- **carbamazepine** (used to treat epilepsy)
- **chlorpromazine** (used to treat psychosis or schizophrenia)
- **loperamide** (used to treat diarrhoea)
- **medicines for pain and/or inflammation** called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indometacin, ibuprofen.

Desmopressin acetate tablets with food or drink
- Before you start treatment with this medicine, your doctor should give you advice about fluid intake.
- When using this medicine for bedwetting or nocturia, keep your **fluid intake to a minimum** from **1 hour before** you take a tablet **until 8 hours** after a dose.
- Avoid swallowing water while swimming to prevent build-up of water in the body.
- You should avoid drinking large amount of fluid while you are being treated with desmopressin acetate tablets, as this could lead to build up of water which dilutes the salt in the body. This can occur with or without warnings or symptoms, which include unusually bad or prolonged headache, feeling or being sick, unexplained weight gain and in serious cases, fits. If you have any of these symptoms, **stop the treatment and contact your doctor at once.**

Pregnancy and breastfeeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, please ask your doctor or pharmacist for advice before taking this medicine. Your doctor will need to monitor your blood pressure whilst on desmopressin acetate tablets due to increased risk of pre-eclampsia. Symptoms of pre-eclampsia include high blood pressure, oedema (swelling due to the build-up of fluid) and proteinuria (protein in the urine).

Driving and using machines
There is no evidence to suggest that desmopressin acetate tablets affect the ability to drive or use machines.

Desmopressin acetate tablets contain lactose
If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine product, as it contains lactose.

3. HOW TO TAKE DESMOPRESSIN ACETATE TABLETS

Always take desmopressin acetate tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Do not take more than the prescribed dose in any 24-hour period.

If you have the impression that the effect of desmopressin acetate tablets is too strong or weak, talk to your doctor or pharmacist.

- Divide the tablets in half orswallow whole.
- **Do not take** Desmopressin acetate tablets **with food**, as the effect of the tablets may be reduced.

The recommended doses are:
- **Diabetes insipidus**
  Your doctor will prescribe the dose most suitable for you. The most common dose in adults and children is one 100 micrograms tablet or one 200 micrograms tablet taken three times a day.
- **Bedwetting (Involuntary nightlyurination)**
  Children (over 5 years) and adults (up to 65 years of age)
  Your usual starting dose is one 200 micrograms tablet at bedtime. Your doctor may increase the dose to two 200micrograms tablets at bedtime depending on how well the bedwetting is controlled. The need for continued treatment is normally checked every three months.
- **Excessive thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland:**
  Your doctor will prescribe the most suitable doses for you based on the concentration of your urine.

If you take more desmopressin acetate tablets than you should
An overdose may lengthen the effect of desmopressin and increase the risk of water build up in the body and low blood salt. Symptoms include fits and unconsciousness. If you take more desmopressin acetate tablets than prescribed, contact your doctor, pharmacist or the nearest hospital immediately.

If you forget to take desmopressin acetate tablets
Do not take a double dose to make up for a forgotten dose.
If you are a patient being treated for bedwetting, do not take desmopressin acetate tablets until the usual time for your next dose.
If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice.

If you stop taking Desmopressin acetate tablets
You should only change or stop your treatment only if advised by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, desmopressin acetate tablets can cause side effects, although not everybody gets them.

Stop the treatment and contact your doctor at once if the following occur
- Excessive fluid intake may lead to a build-up of water which dilutes the salt in the body in severe cases. This can become a serious problem and may lead to convulsions. Early symptoms may include an unusually bad or prolonged headache, feeling or being sick and unexplained weight gain,
- **allergic reaction,** rash, itching, fever, swelling of the mouth, tongue or airways causing difficulties in swallowing or breathing.

Tell your doctor or pharmacist if you notice any of the following other side effects, or if you notice any not listed:
- Headache.
- Stomach pain.
- Emotional disturbances including aggression in children.

If you experience one or more of these side effects or any other side effects not listed in the leaflet, please contact your doctor or pharmacist immediately.

Reporting of side effects:
If you get any side effects, talk to your doctor, pharmacist 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 website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card on Google Play or Apple App store.

5. HOW TOSTORE DESMOPRESSIN ACETATE TABLETS

Keep out of the sight and reach of children.
Do not store desmopressin acetate tablets above 30°C.
Keep the container tightly closed in order to protect from moisture.
Do not use desmopressin acetate tablets after the expiry date, stated on the pack. Always return any leftover medicine to your pharmacist.
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 to protect the environment.

6. FURTHER INFORMATION

What Desmopressin acetate tablets contain
- the active substance (the ingredient that makes the tablet work) is desmopressin acetate. Each tablet contains either 100 micrograms or 200 micrograms of the active substance.
- the other ingredients of the tablets are lactose monohydrate, potato starch, povidone and magnesium stearate.

What Desmopressin acetate tablets look like and contents of the pack

Desmopressin acetate tablets are white, round, and marked with a break line on one side.

The tablets are in plastic containers containing 7, 10, 15, 20, 30, 90, 100 or 250 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder
Torrent Pharma (UK) Ltd
3rd Floor, Nexus Building
4 Gatwick Road
Crawley
West Sussex
RH10 9BG
United Kingdom

Manufacturer
Inpac AS, Gjellebekkstubben 10, 3420 Lierskogen, Norway.

The leaflet was last revised in 03/2025.

8100433-7803

Pharma Code

Pharma Code

Colour Black

LOCATION : ---	**COUNTRY : UK**	**Supersedes A/W No.:**		
SIZE : 180 x 290 mm_Front/Back Side		**CODE : 8100433-7803**	**V. No.: 01**	**DATE : 11-03-2025**
REMARK :				
SUBSTRATE :				

Activities	Department	Name	Signature	Date
Prepared By	**Pkg.Dev**			
Reviewed By	**Pkg.Dev**			
Approved By	**Quality**			

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.