Proposed packaging material		
Code	MINSPR(2.5ml)-I-ID-03.01	
Size		
Submission	☐NDA ☐Renewal ☒Variation change detail no.:	
Code of previous version	MINSPR(2.5ml)-I-ID-02-.01	
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Reference	☒CCDS version: 2012/08 Ver 04 ☐Core PIL version:	Reference
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MINIRIN®

Desmopressin acetate
Nasal Spray 10mcg/dose (0.1 mg/ml)

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 0.1 mg desmopressin acetate equivalent to 89 µg desmopressin, and 0.1 mg benzalkonium chloride. Excipients: Benzalkonium chloride (solution), sodium chloride, citric acid monohydrate (E 330), disodium phosphate dihydrate, and purified water.

PHARMACEUTICAL FORM

Nasal spray, solution.

THERAPEUTIC INDICATIONS

Minirin Nasal Spray is indicated for the management of central diabetes insipidus and testing of renal concentration capacity in adults and children.

POSOLOGY AND METHOD OF ADMINISTRATION

Central diabetes insipidus:
Individual dosing after testing. The normal dose in adults is 10-20 mcg 1-2 times daily. in children 10 mcg 1-2 times daily.

Testing of renal concentration capacity
Adults : Two sprays into each nostril (a total of 40 micrograms)
Children : (1-15 years): One spray into each nostril (a total of 20 micrograms).

CONTRAINDICATIONS

MINIRIN® must NOT be used in:

- habitual or psychogenic polydipsia (resulting in a urine production exceeding 40 ml/kg/24 hours);
- syndrome of inappropriate ADH secretion (SIADH);
- known hyponatraemia;
- known or suspected cardiac insufficiency and other conditions requiring treatment with diuretics;
- moderate and severe renal insufficiency (creatinine clearance below 50 ml/min);
- hypersensitivity to the active substances or to any of the excipients.
- Before prescribing MINIRIN, the diagnoses of alcohol abuse should be excluded

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

MINIRIN® nasal formulations should be used only when treatment with oral formulations is inappropriate.

When MINIRIN® is prescribed it is recommended to:

- start with the lowest dose
- ensure compliance with fluid restriction instructions
- increase dose progressively, with caution
- ensure that children administration is under adult supervision in order to control the dose intake

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MINIRIN® should be used with caution in:
- the treatment of small children and elderly patients
- fluid and/or electrolyte imbalance
- risk of increased intracranial pressure

All patients receiving MINIRIN should be observed for the following signs or symptoms associated with Hyponatraemia: headache, nausea/vomiting, decreased serum sodium, weight gain, restlessness, fatigue, lethargy, disorientation, depressed reflexes, loss appetite, irritability, muscle weakness, muscle spasms or cramps and abnormal mental status such as hallucinations, decreased consciousness, and confusion. Severe symptoms due to an extreme decrease in serum sodium and plasma osmolality may include one or a combination of the following: seizure, coma, and/or respiratory arrest.

In order to decrease the risk of water intoxication with Hyponatraemia, fluid restriction is recommended. Careful fluid intake restriction is particularly important in pediatric and geriatric patients because these patients are at greater risk of developing Hyponatraemia. More frequent monitoring of serum sodium levels is recommended in the following patients: those with conditions associated with fluid and electrolyte imbalance, such as cystic fibrosis, heart failure, renal disorders, habitual or psychogenic polydipsia or those taking concomitant drugs that may cause Hyponatraemia (*see Drug Interactions).*

Elderly patients, patients with low plasma sodium levels and patients with high 24-hour urine volumes (above 2.8 to 3 litres) have an increased risk of developing hyponatraemia. Elderly patients may be more sensitive to the antidiuretic effect of the usual adult dose of DDAVP. Patients over the age of 65 should be closely observed for possible water retention due to over ingestion of fluids. Fluid intake should be carefully adjusted to prevent over-hydration.

In patients with urgency/urge incontinence, organic causes for increased micturition frequency or nocturia (e.g. benign prostatic hyperplasia, urinary tract infection, bladder stones/tumours), polydipsia or poorly controlled diabetes mellitus, the specific cause of the symptoms should be dealt with primarily.

To prevent hyponatraemia, caution must be exercised and particular attention should be paid to fluid retention and frequent checks made of sodium plasma levels in the following circumstances;
- concomitant treatment with drugs that are known to induce inappropriate ADH secretion syndrome (SIADH), e.g. tricyclic antidepressants, SSRIs, chloropromazine and carbamazepine as well as some antidiabetics of the sulfonylurea group such as glibenclamide.
- concomitant treatment with NSAID preparations.

Treatment with desmopressin should be carefully adjusted during acute illness characterized by fluid and/or electrolyte imbalance such as systemic infections, fever and gastroenteritis.

Experience from clinical use indicates a risk of severe hyponatraemia in association with the nasal formulations of desmopressin, when it is used in the treatment of central diabetes insipidus.

MINIRIN® 0.1 mg/ml nasal spray may cause bronchospasm due to the presence of benzalkonium chloride in this product.

At testing of renal concentration capacity
When used diagnostically, fluid intake should be restricted to a maximum of 0.5 L to satisfy thirst for 1 hour before administration until 8 hours after administration.

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Following diagnostic testing for diabetes insipidus or renal concentration, care should be taken to prevent fluid overload. Fluid should not be forced, orally or parenterally, and patients should only take as much fluid as they require to satisfy thirst.

Chronic administration of MINIRIN® may result in changes to nasal mucosa. Nasal mucosa abnormalities (such as scarring and edema) due to chronic administration, or due to other causes (nasal blockage, nasal mucosal atrophy, severe atrophic rhinitis, recent nasal surgery such as transsphenoidal hypophysectomy) may cause erratic, unreliable absorption. Avoid use of MINIRIN® in such patients and consider use of other formulations of desmopressin acetate given by other routes of administration.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
The concomitant administration of Desmopressin Acetate Nasal Spray with other drugs that may increase the risk of water intoxication with Hyponatraemia, (e.g., tricyclic antidepressants, selective serotonin re uptake inhibitors, chlorpromazine, opiate analgesics, NSAIDs, lamotrigine, oxybutynin and carbamazepine) requires more frequent serum sodium monitoring [see Warnings and Precautions and Adverse Reactions.

Glibenclamide and lithium may attenuate the antidiuretic effect of desmopressin. Desmopressin may enhance the effect of antihypotensive and attenuate the effect of antihypertensive medicinal products. It is unlikely that desmopressin interacts with pharmaceuticals affecting hepatic metabolism, since desmopressin has not been shown to undergo any significant liver metabolism in *in vitro* studies with human microsomes. However, formal interaction studies *in vivo* have not been performed.

PREGNANCY AND LACTATION

Pregnancy

Risk summary
Prolonged experience with desmopressin in pregnant women over several decades, based on the available published data and case reports, did not identify a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In addition, in vitro studies with human placenta demonstrate poor placental transfer of desmopressin. No adverse developmental outcomes were observed in animal reproduction studies with administration of desmopressin during organogenesis to pregnant rats and rabbits at doses approximately less than 1 and 38 times, respectively, the maximum recommended human dose based on body surface area (mg/m2) (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 - 4 % and 15 - 20%, respectively.

Caution should be exercised when prescribing to pregnant women. Blood pressure monitoring is recommended due to the increased risk of pre-eclampsia.

Data
Animal Data
Desmopressin acetate at up to 50 ng/kg/day was given by subcutaneous injection to pregnant rats, from gestation day 1 to 20 during the period of early embryonic development and organogenesis without teratogenic effects. Desmopressin acetate at up to 10 mcg/kg/day was given to pregnant rabbits by subcutaneous injection from gestation day 6 to 18 during fetal organogenesis without

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teratogenic effects. These doses of desmopressin acetate represent approximately <1 times (rat) and 38 times (rabbit) the maximum recommended human dose based on body surface area (mg/m2).

Lactation

Risk Summary

Breastfeeding is not expected to result in clinically relevant exposure of the infant to desmopressin following maternal intranasal administration. Desmopressin is poorly transferred into human breastmilk at negligible amounts (see Data). There is no information on the effects of desmopressin on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Desmopressin Acetate Nasal Spray and any potential adverse effects on the breastfed infant from Desmopressin Acetate Nasal Spray or from the underlying maternal condition.

Data

A trial was conducted in six healthy lactating women, at greater than 4 months postpartum, to evaluate intranasal administration of 300 mcg single dose of another desmopressin product (7.5 times the recommended adult dose of Desmopressin Acetate Nasal Spray). Samples of maternal plasma and breastmilk were obtained at 0, 30, 60, 120, 240, 360 and 480 min after the drug administration. At 8 hours after dose intake, the levels in the milk ranged between 4.16 and 101 pg/ml, and the plasma levels ranged between 40 and 242 pg/ml. The total amount of desmopressin present in the milk over the 8 hours ranged between 491 pg and 16 ng, which corresponds to 0.0001 - 0.005% of the administered dose to the breastfeeding mother.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

UNDESIRABLE EFFECTS

Summary of the safety profile

The most serious adverse reaction with desmopressin is hyponatraemia, see below under "Description of selected adverse reactions".

The most commonly reported adverse reactions during treatment were nasal congestion (27%), high body temperature (15%) and rhinitis (12%). Other common adverse reactions were headache (9%), upper respiratory tract infection (9%), gastroenteritis (7%), abdominal pain (5%). Anaphylactic reactions have not been seen in clinical trials but spontaneous reports have been received.

Tabulated summary of adverse reactions

The below table is based on the frequency of adverse drug reactions reported in clinical trials with nasal MINIRIN® conducted in children and adults for treatment of central diabetes insipidus, primary nocturnal enuresis and at testing of renal concentration capacity (N=745).

MedDRA Organ Class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to < 1/100)**
Metabolism and nutrition disorders			Hyponatraemia
Psychiatric disorders		Insomnia, Affect lability**, Nightmare**, Anxiety**, Aggression**	

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Nervous system disorders		Headache*	
Respiratory, thoracic and	Nasal congestion	Nosebleed, Upper respiratory	
Mediastinal disorders	Rhinitis,	Tract infection**	
Gastrointestinal disorders		Gastroenteritis, Nausea*, Abdominal pain*	Vomiting*

*Reported in connection with hyponatraemia.
** Above all reported in children and adolescents.

Description of selected adverse reactions
The most serious adverse reaction with desmopressin is hyponatraemia, which may give symptoms like headache, nausea, vomiting, weight increase, malaise, abdominal pain, muscle spasms, dizziness, confusion, decreased consciousness and in serious cases convulsions and coma. The cause of the potential hyponatraemia is the anticipated antidiuretic effect.

Paediatric population
Hyponatraemia is reversible and in children it is often seen to occur in relation to changes in daily routines affecting fluid intake and/or perspiration.
Special precautions should be observed in children, see Special warnings and precautions for use.

Special populations
Elderly patients and patients with low serum sodium levels may have an increased risk of developing hyponatraemia (see Special warnings and precautions for use).

Post-Market Adverse Drug Reactions
Desmopressin is a potent antidiuretic, which may lead to water intoxication and/or Hyponatraemia. Hyponatraemia has been reported at an approximate rate of 5 cases per 10 million doses from worldwide post marketing experience in patients treated with DDAVP intranasal formulations. The reported rate for DDAVP oral formulations worldwide is considerably less at about 1 case per 10 million doses. Unless properly diagnosed and treated, Hyponatraemia can be fatal. Therefore, fluid restriction is recommended and should be discussed with the patient and/or guardian. Careful medical supervision is required. Severe general allergic reactions have been reported. Other adverse events reported include: dehydration, somnolence, fatigue, hypertension, dyspnea, diarrhea, pruritis, muscle spasms, rash and urticaria, peripheral edema, chest pain and chills.

Adverse Event Reporting
If you notice any of the adverse events reactions mentioned above, or any adverse reactions not listed in this leaflet, please contact your doctor or nurse. You can also report these side effects to Ferring or the national reporting system provided below. Reporting side effects helps to gather more information about the safety of this medication.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

Pusat MESO/Farmakovigilans Nasional
Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif

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Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp: 021 – 4244691 Ext.1079
Email: pv-center@pom.go.id
Web : http://e-meso.pom.go.id/

OVERDOSE

Toxicity

Overdosage leads to prolonged duration of action with an increased risk of fluid retention and hyponatraemia. Even normal doses may cause water intoxication in association with a high fluid intake. Doses exceeding 0.3 µg/kg i.v. and 2.4 µg/kg intranasally have together with fluid intake caused hyponatraemia and convulsions in children and adults. However, 40 µg administered intranasally to a 5-month-old baby and 80 µg administered intranasally to a 5-year-old produced no symptoms. 4 µg administered parenterally to a newborn produced oliguria and weight-gain.

Symptoms

The same symptoms as for water intoxication. Headache, nausea. Fluid retention, hyponatraemia, hypoosmolality, oliguria, CNS depression, convulsions, pulmonary oedema, drowsiness, problems with passing urine, and rapid weight gain due to fluid retention. See also Undesirable effects.

Treatment

In case of overdosage, reduce the dosage, decrease the frequency of administration, or discontinue Desmopressin Acetate Nasal Spray. There is no known specific antidote for desmopressin acetate.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: vasopressin andanalogues. ATC code: H01B A02.
MINIRIN® contains desmopressin, a structural analogue of the natural pituitary hormone arginine vasopressin. The difference lies in that the amino group in cysteine has been removed and Larginine has been substituted by D-arginine. This results in a considerably longer duration of action with intranasal administration and a complete lack of pressor effect in the dosages used clinically.

The change in structure of arginine vasopressin to desmopressin acetate resulted in a decreased vasopressor action and decreased actions on visceral smooth muscle relative to the enhanced antidiuretic activity, so that clinically effective antidiuretic doses were usually below threshold levels for effects on vascular or visceral smooth muscle.

The antidiuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water reabsorption in the kidney, and hence reducing urine production.

The use of MINIRIN Nasal Spray in patients with central diabetes insipidus reduces urinary output, increases urine osmolality, and decreases plasma osmolality.

PHARMACOKINETIC PROPERTIES

Absorption

Following intranasal administration of MINIRIN®, approximately 10-20% of a dose is absorbed through the nasal mucosa. Patients with nasal congestion may require an increased dosage. Following intranasal administration of usual doses of MINIRIN® in patients with neurohypophyseal diabetes insipidus, antidiuretic effects occur within 1 hour, peak in 1-5 hours, persist for 8-20 hours, and then abruptly end over a period of 60-90 minutes. Duration of action varies among individuals with a specific dose. The relatively prolonged duration of action of MINIRIN® may result from slower enzymatic

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inactivation of desmopressin than vasopressin or from sequestration of MINIRIN® in a membrane compartment.

Distribution
The distribution of desmopressin has not been fully characterized.

Metabolism
The in vivo metabolism of desmopressin has not been studied. In in vitro studies, desmopressin was no inhibitor of CYP1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1 or 3A4.

Excretion
The mean terminal half-life of desmopressin is estimated to 2.8 hours. The disappearance of DDAVP from plasma after intranasal administration follows an exponential time course with halflives ranging between 0.4 to 4 hours after intranasal application. The metabolic fate of desmopressin is unknown. Unlike vasopressin, desmopressin apparently is not degraded by aminopeptidases or other peptidases that cleave oxytocin and endogenous vasopressin in the plasma during late pregnancy.

INCOMPATIBILITIES
Not applicable.

SHELF LIFE
2 years.

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C.

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NATURE AND CONTENTS OF CONTAINER

MINIRIN® nasal spray is propelled by a manual dose pump without propellant gas. The spray pump is constructed to administer 100 µl solution (= 10 µg desmopressin acetate) per spray dose.

Pack size: Box, glass bottle @ 2.5ml. Reg.No.: XXXXXXXXXXXXXXX

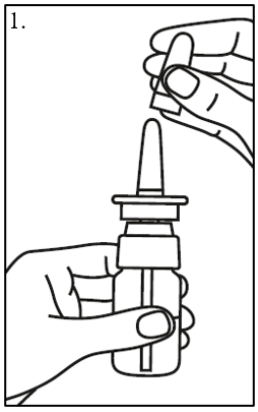
SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Before MINIRIN® nasal spray is used for the first time, prime the pump by pressing it downwards 6 times, or until an even spray is obtained. If the spray has not been used for 3 days it will be necessary to prime the pump again by pressing it downwards twice or until an even spray is obtained.

Instructions for use:

The patient should blow his/her nose before using the spray.

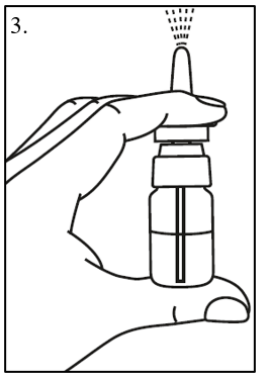
1.



1. Remove the protection cap.

2. Control that the end of the tube inside the bottle is submerged in the liquid.

3.



3. Re-prime the pump if the spray has not been used within the last 3 days by pressing down twice

4. Once it has been primed, the pump delivers one dose each time pressure is applied.

5.

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5. Insert the applicator straight into the nostril.
6. When a higher dose is needed, spray alternatively into each nostril.
7. Replace cap after use and store the bottle in an upright position.

MANUFACTURER
Ferring GmbH
Wittland 11, 24109 Kiel, Germany

IMPORTED BY
PT Ferring Pharmaceuticals Industry Tangerang
Selatan – Indonesia

HARUS DENGAN RESEP DOKTER DATE OF REVISION
20 June 2025

Proposed packaging material		
Code	MINSPR-I(PIL)-ID-02.01	
Size	N/A	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: 186724	
Code of previous version	MINSPR-I(PIL)-ID-01.02	
Changes	MA Transfer to Ferring	
Reference	☐CCDS version: ☐ Core PIL version:	☒SPC country/version/date: EU, Version 3.1, 06/2015 ☐LAC no.:
Name & Date	INS, 19-May-2021	

Informasi untuk pasien
Minirin Semprot Hidung 0.1mg/mL
Desmopressin Asetat

Bacalah leaflet ini seluruhnya dengan cermat sebelum Anda mulai menggunakan obat ini karena leaflet ini berisi informasi penting untuk Anda.
- Simpanlah leaflet ini, sebab Anda mungkin perlu membacanya lagi dikemudian hari.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter atau apoteker Anda.
- Resep obat ini sudah dibuat hanya untuk Anda. Jangan berikan obat ini pada orang lain. Obat ini mungkin membahayakan mereka, meskipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, bicarakan dengan dokter atau apoteker Anda. Termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa saja yang ada dalam leaflet ini?

1. Apa yang dimaksud dengan MINIRIN Semprot Hidung dan apa tujuan penggunaannya

MINIRIN Semprot Hidung mengandung desmopressin asetat yang berfungsi sebagai hormon vasopressin alami. Hormon ini mengatur kemampuan ginjal untuk mengkonsentrasikan kemih/urin.
MINIRIN Semprot Hidung digunakan untuk :
- Pengobatan *Central Diabetes Insipidus* (gangguan bagian belakang otak/pituitary) yang mengakibatkan rasa haus dan volume urin yang ekstrim
- Pengujian/tes terhadap kapasitas konsentrasi ginjal

2. Apa yang perlu Anda ketahui sebelum menggunakan MINIRIN Semprot Hidung

Jangan gunakan MINIRIN Semprot Hidung jika:
- Anda alergi terhadap desmopressin asetat atau salah satu dari bahan lain di dalam obat ini (tertera di dalam bagian 6).
- Anda menderita polidipsia (rasa haus yang ekstrim)
- Anda menderita gangguan jantung dan penyakit lain yang menggunakan pengobatan diuretik
- Fungsi ginjal Anda mengalami gangguan
- Anda memiliki tingkat serum natrium yang rendah
- Anda mengalami gangguan pengeluaran/sekresi hormon

Peringatan dan tindak pencegahan
Bicaralah dengan dokter Anda sebelum menggunakan Minirin, jika :
- Anda berusia 65 tahun ke atas
- Anda memiliki risiko peningkatan tekanan di dalam tengkorak

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Minirin Semprot Hidung sebaiknya digunakan hanya ketika pengobatan dengan formulasi oral (tablet atau *oral lyophilisate*) tidak sesuai.
Ketika digunakan untuk pengujian kapasitas konsentrasi ginjal, asupan cairan untuk memuaskan rasa haus harus dibatasi pada minimum 1 jam sebelum dan hingga sekurang-kurangnya 8 jam sesudah menggunakan Minirin.

Minirin sebaiknya digunakan dengan hati-hati ketika keseimbangan cairan terganggu. Berkonsultasilah dengan dokter Anda jika Anda mengalami gangguan keseimbangan cairan dan/atau garam di dalam tubuh Anda sehubungan dengan penyakit yang parah/akut.

Obat lain dan MINIRIN Semprot Hidung

Beritahu dokter Anda apabila Anda pernah memiliki atau mungkin memiliki kondisi medis berikut:
- terlalu sedikit atau terlalu banyak cairan dalam tubuh
- memiliki riwayat infeksi pada hidung, hidung berair, atau hidung tersumbat
- penyakit darah rendah
- penyakit fibrosis kistik atau penyakit lain yang menyebabkan terganggunya cairan elektrolit
- penurunan kondisi medis akibat terganggunya cairan elektrolit
- penyakit akibat pembekuan darah
- kondisi medis serius pada fungsi kandung kemih

Beritahu dokter atau apoteker Anda jika Anda sedang, belum lama ini, atau mungkin mengkonsumsi obat lain apapun, termasuk obat yang didapat tanpa resep dokter.

Obat berikut ini dapat meningkatkan efektivitas Minirin dan menimbulkan efek samping:
- Clofibrate (untuk terapi kolesterol tinggi dalam darah)
- Chlorpromazine (terapi skizofrenia)
- Carbamazepine (terapi epilepsi)
- Antidepresan trisiklik
- Penghambat ambilan kembali serotonin (terapi depresi)
- Obat anti-inflamasi nonsteroid (anti nyeri dan anti inflamasi)

Obat berikut dapat mengurangi efektivitas Minirin:
- Glibenclamid (obat diabetes)
- Lithium (anti depresi)
- Minirin dapat meningkatkan efek beberapa obat penurun tekanan darah. Minirin juga dapat menurunkan efek obat peningkat tekanan darah.

Kehamilan dan menyusui
- Beritahukan dokter Anda jika Anda hamil atau berencana untuk hamil atau sedang menyusui. Minirin Nasal Spray dapat digunakan pada wanita hamil jika diperlukan. Dokter akan memberitahukan risiko dan manfaatnya.
- Jangan menyusui jika menggunakan obat ini.
- Zat aktif dalam Minirin Nasal Spray terdistribusi ke dalam air susu. Untuk itu, obat tidak direkomendasikan pada kondisi menyusui.

Berkendara dan menggunakan mesin
Minirin tidak atau menimbulkan efek yang sangat kecil (sehingga dapat diabaikan) terhadap kemampuan berkendara dan menggunakan mesin.

Proposed packaging material		
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Size	N/A	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: 186724	
Code of previous version	MINSPR-I(PIL)-ID-01.02	
Changes	MA Transfer to Ferring	
Reference	☐CCDS version: ☐ Core PIL version:	☒SPC country/version/date: EU, Version 3.1, 06/2015 ☐LAC no.:
Name & Date	INS, 19-May-2021	

MINIRIN SEMPROT HIDUNG mengandung benzalkonium klorida
Benzalkonium klorida mungkin menyebabkan bronkospasma atau penyempitan saluran pernafasan.

3. Bagaimana menggunakan MINIRIN SEMPROT HIDUNG

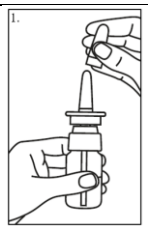
Selalu gunakan obat ini sesuai dengan petunjuk dan dosis yang diberikan oleh dokter Anda. Tanyakan kembali kepada dokter Anda jika tidak yakin.
Dosis bersifat individual dan dokter akan memberikan resep dengan dosis yang paling sesuai untuk Anda.

Diabetes insipidus:
Dosis yang direkomendasikan untuk orang dewasa adalah 10-20 mcg sebanyak 1-2 kali sehari. Dosis pada anak 10 mcg 1-2 kali sehari.

Pengujian kapasitas konsentrasi ginjal:
Dewasa : 2 spray kedalam tiap lubang hidung (dosis total 40 mcg)
Anak (1-15 tahun) : 1 spray kedalam tiap lubang hidung (dosis total 20 mcg)

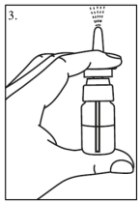
Petunjuk penggunaan
Sebelum menggunakan MINIRIN Semprot Hidung untuk pertama kali, pancing pompa dengan cara menekannya ke bawah 6 kali, atau hingga diperoleh semprotan yang merata. Jika alat semprot belum digunakan selama 3 hari sebelumnya, maka pompa harus dipancing lagi dengan cara menekannya ke bawah dua kali atau hingga diperoleh semprotan yang merata.

Petunjuk penggunaan:
Pasien harus membuang ingus sebelum menggunakan semprotan.



1. Lepaskan tutup pelindung

2. Pastikan ujung tabung di dalam botol terendam dalam cairan.



3. Pancing kembali bila pompa tidak digunakan selama 3 hari dengan cara menekannya ke bawah dua kali

4. Setelah dipancing, pompa akan menyemprotkan satu dosis setiap kali tekanan diberikan.

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5. Masukkan aplikator langsung ke dalam lubang hidung

6.Bila dosis yang lebih tinggi dibutuhkan, semprotkan secara bergantian ke setiap lubang hidung.

7. Pasang kembali tutup setelah digunakan dan simpan botol dalam posisi tegak.

Jika Anda menggunakan Minirin lebih banyak daripada yang harus Anda gunakan:

Jika Anda telah menggunakan obat ini lebih banyak daripada yang harus Anda gunakan, atau jika ada anak yang sudah menggunakan obat ini tanpa disengaja, harap hubungi dokter Anda atau rumah sakit untuk memperoleh pendapat tentang risiko dan nasihat tentang tindakan yang harus diambil. Kurangi konsumsi air. Overdosis obat ini menyebabkan sakit kepala, mual, kram.

Jika Anda lupa menggunakan Minirin:
Jangan menggunakan dosis ganda untuk menggantikan dosis yang terlupa, obat diberikan pada jadwal dosis berikutnya.
Jika anda menghentikan Minirin Semprot Hidung, Anda dapat mengalami gejala seperti sebelum pengobatan.
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyalah kepada dokter atau apoteker Anda

4. Efek samping yang mungkin terjadi

Seperti obat lainnya, obat ini dapat memberikan efek samping, yang mungkin tidak semua orang akan mengalaminya.

Jika asupan cairan tidak dibatasi menurut petunjuk di atas, maka cairan dalam jumlah yang tidak normal dapat berakumulasi dalam tubuh, yang mungkin mengakibatkan sakit kepala, mual/muntah, bertambahnya berat badan, dan kasus serius yakni kejang-kejang.

Sangat umum (mungkin timbul pada lebih dari 1 dari 10 pengguna):
Hidung tersumbat, peradangan hidung atau selaput lendirnya (rhinitis), suhu tubuh naik.
Umum (mungkin timbul pada hingga 1 dari 10 pengguna):
Sulit tidur, perubahan suasana hati, mimpi buruk, beberapa gejala kecemasan, perasaan tertekan, sakit kepala, gangguan pencernaan, mual, sakit perut, mimisan, infeksi saluran pernafasan sebelah atas.
Tidak Umum (mungkin timbul pada hingga 1 dari 100 pengguna):
Tingkat serum potassium yang rendah, muntah.
Frekuensi yang tidak diketahui (tidak dapat ditaksir dari data yang tersedia)

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Reaksi alergi serius dengan demam, ruam, pembengkakan, dan kadang-kadang tekanan darah rendah, dehidrasi, kebingungan, kejang-kejang, koma, pusing, kantuk, tekanan darah naik, sesak nafas, diare, gatal-gatal, rasa gatal-gatal dengan bintik merah dan pembengkakan, kejang otot, letih, pembengkakan tangan dan kaki, sakit dada, menggigil, berat badan bertambah.

Pelaporan efek samping

Jika Anda mendapatkan efek samping diatas, hubungi dokter atau perawat Anda. Hal yang sama berlaku untuk efek samping yang tidak tercantum dalam leaflet ini. Anda juga dapat melaporkan efek samping tersebut ke sistem pelaporan nasional dibawah ini. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

Pusat MESO/Farmakovigilans Nasional

Direktorat Pengawasan Keamanan, Mutu, dan Ekspor
Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp : 021 – 4244691 Ext.1079
Email : pv-center@pom.go.id
Web: http://e-meso.pom.go.id/

5. Bagaimana cara penyimpanan MINIRIN Semprot Hidung

Proposed packaging material		
Code	MINSPR-I(PIL)-ID-03.01	
Size	N/A	
Submission	☐NDA ☐Renewal ☒Variation change detail no.:	
Code of previous version	MINSPR-I(PIL)-ID-02.01	
Changes	MA Transfer to Ferring	
Reference	☐CCDS version: ☐ Core PIL version:	☒SPC country/version/date: EU, Version 3.1, 06/2015 ☐LAC no.:
Name & Date	HINI, 24 June 2025	

Jauhkan dari jangkauan anak-anak.

Simpan pada ruangan bersuhu dibawah 25◦C.

Jangan gunakan obat ini lewat dari tanggal kadaluarsa yang tercantum di label. Tanggal kadaluarsa produk mengacu pada hari terakhir pada bulan yang dimaksud. Setelah pengobatan, buang seluruh larutan yang tidak terpakai.

Jangan buang obat apa pun melalui atau ke air limbah atau limbah rumah tangga. Tanyakan pada apoteker Anda bagaimana membuang obat yang tidak lagi Anda gunakan. Tindak pencegahan ini akan membantu dalam melindungi lingkungan hidup.

6. Isi kemasan dan informasi lain

Apa isi MINIRIN SEMPROT HIDUNG?

- Zat aktif : Desmopressin asetat.
  Satu mililiter (ml) larutan mengandung 0.1 mg Desmopressin asetat.

- dan air.Bahan lain : benzalkonium klorida (pengawet), asam sitrat (E 330), disodium fosfat dihidrat, natrium klorida

Tampilan MINIRIN SEMPROT HIDUNG dan isi kemasan

Dus, botol kaca @ 2.5mL
No.Reg: DKIXXXXXXXXXXX

Produsen Ferring
GmbH
Wittland 11, Kiel
Germany

Diimpor oleh:
PT Ferring Pharmaceuticals Industry Tangerang
Selatan – Indonesia

HARUS DENGAN RESEP DOKTER Leaflet ini terakhir direvisi pada June 2025