

# TAN FÁCIL



**Bomba D-mine de 5 mg/ml de dacepton en frascos de 20 ml.**

Un sistema de bomba de infusión volumétrica basado en mg intuitivo y fácil de usar desarrollado específicamente para pacientes con enfermedad de Parkinson. El llenado automático garantiza un manejo seguro de medicamentos y con hasta 5 tasas diferentes programables en unos pocos pasos simples, los tiempos de entrenamiento del usuario se redujeron. La bomba D-mine apoya una mayor autosuficiencia y movilidad para sus pacientes con parkinson!



Uso subcutáneo

**Dacepton®**  
Clorhidrato de apomorfina

# Indicación y aplicación de la bomba D-mine PUMP

La bomba de DMI es un dispositivo médico seguro y confiable  
Infusión subcutánea de clorhidrato de apomorfina  
5 mg/ml en frascos de 20 ml) para el tratamiento de la enfermedad de Parkinson.

La bomba de infusión está conectada al cuerpo con un conjunto de infusión y el medicamento se entregará continuamente. Esta forma de terapia se denomina terapia de bomba de infusión de apomorfina continua.

Antes de comenzar la administración, el medicamento se transfiere desde el frasco al depósito de bomba D-mine®. Este proceso es automáticamente realizado por la bomba.

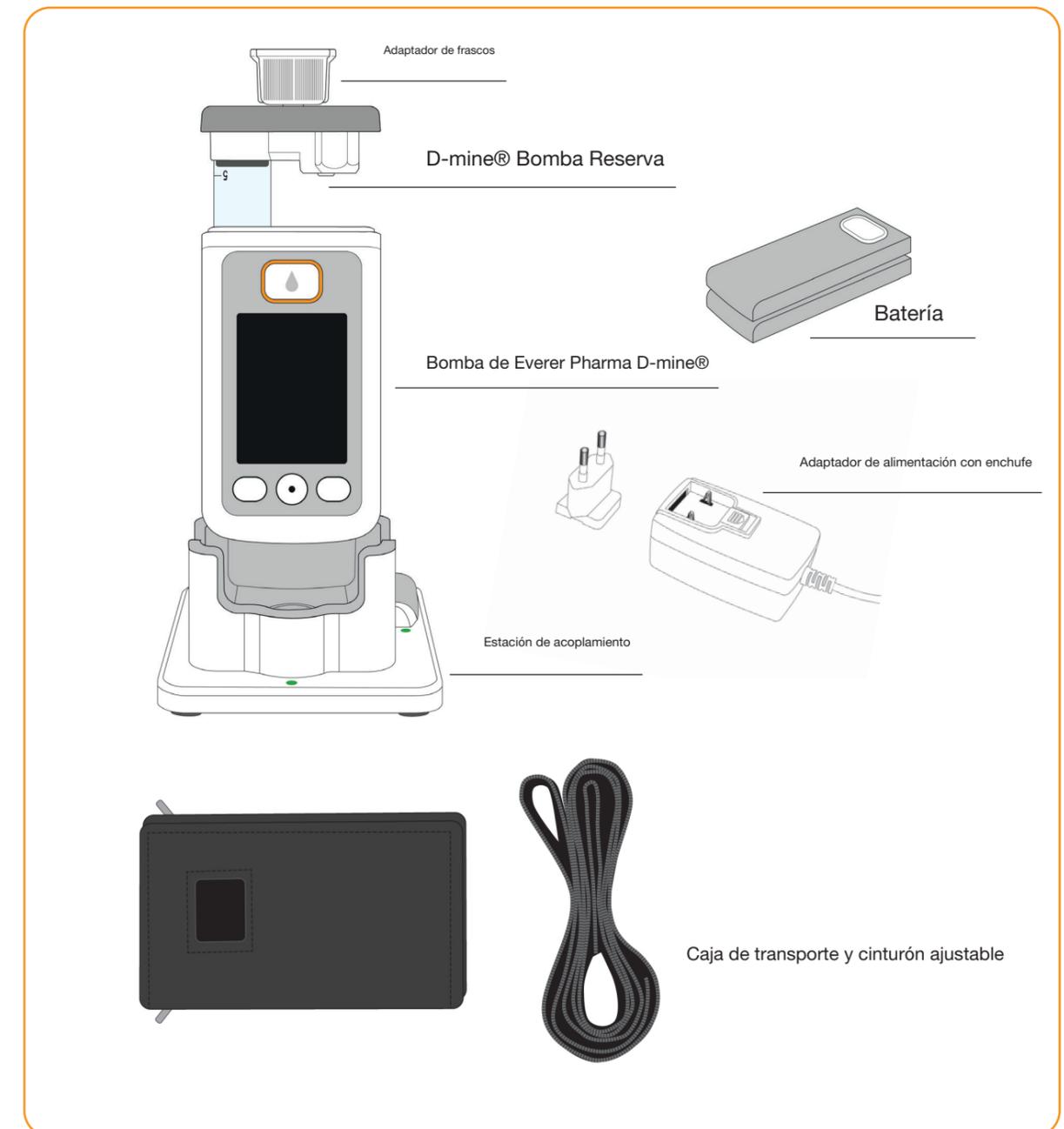
La cantidad de apomorfina que se entrega continuamente durante un día se denomina tasa de flujo base o tasa base. La configuración de la tasa base de un día se denomina perfil básico y se establece para los requisitos de dosis individuales.

El bolus es una dosis adicional de apomorfina que se libera cuando se presiona un botón de bolus específico. La dosis y la cantidad de bolus también están preestablecidas según sea apropiado para los requisitos específicos del paciente. El perfil básico y la configuración del bolo son determinados por un profesor de salud de acuerdo con las instrucciones del especialista en defunción de Parkinson.

## Antes de usar la bomba

- La bomba debe preestablecerse desde el profesional de la salud hasta la dosis prescrita y el paciente debe ser entrenado de acuerdo con las instrucciones para el uso del sistema de bomba.
- La bomba D-mine® controla la administración del medicamento. Funciona solo con el depósito de bomba D-mine®.
- El embalaje del embalaje de los embalajes, los adaptadores, los conjuntos de infusión y los frascos con el medicamento es estéril. Estos artículos no pueden usarse si su embalaje está dañado o faltado.
- ¡Los productos estériles no deben reutilizarse!

## Accesorios de bomba D-mine®



# Elementos operativos



## Pantalla de pantalla

La bomba está equipada con una pantalla a color iluminada que proporciona información importante para su terapia.

El título muestra información general, como el tiempo y el estado de carga de la batería recargable. El dispositivo le muestra el progreso cuando opera la bomba.

En las dos secciones de texto se muestra la información más importante sobre el funcionamiento y control de la bomba.

La parte del botón de función en el borde inferior muestra el significado de la función Botón.

## Botón de bolus

El botón de bolus permite la entrega rápida de bolos.

## Botón de función

Se proporcionan tres botones de función para operar la bomba. Estos están debajo de la pantalla. El significado de los tres botones de función cambia, dependiendo de los comandos necesarios para operar la función seleccionada.

## Botón de liberación

El reservorio se inserta en la bomba y se encuentra en su lugar audíblemente. Puedes desbloquear el reservorio. Presione el botón de liberación en el lado derecho de la bomba.

# Configuración de la bomba D-in®

Antes de comenzar la infusión, la bomba debe llenarse con medicamentos.

## I. Configuración de verificación

En la pantalla principal, debe verificarse la siguiente información:

- el tiempo está fijado correctamente
- No hay error en la visualización
- La configuración de la dosis indicada es correcta
- detención de la entrega del medicamento (el área de diálogo de la pantalla está gris)

## ii. Preparar los materiales

- un nuevo frasco de apomorfina
- un nuevo depósito de la bomba de minas d
- Estación de acoplamiento para colocar la bomba en posición vertical
- un nuevo conjunto de infusión
- Hisopones, desinfectante o similares y parches

## iii. conectar y llenar el reservorio 1. Prepare un depósito de bomba de mina d

Lávate las manos bien antes de tocar partes estériles.

**⚠ Nunca use un embalaje dañado. El embalse ya no será estéril y puede estar sucio.**

Retire el embalaje estéril del embalaje.



## 2. Conecte el depósito a la bomba

Conecte el depósito en la abertura de la bomba como se muestra. El reservorio debe ser engañado con un clic audible.

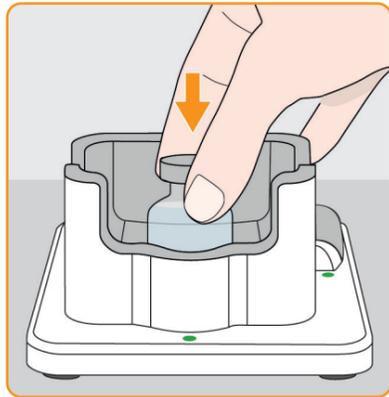


La bomba reconoce que se ha insertado un depósito. Si el reservorio es nuevo, primero debe llenarse con medicamentos.

### 3.Preparar un frasco

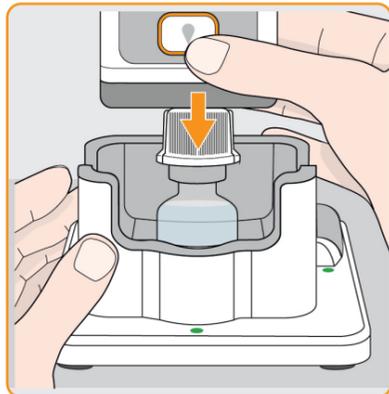
Retire el nuevo frasco del embalaje  
La gorra naranja. Luego limpie el sector del frasco  
Con un hisopo estéril.

Coloque el frasco en el soporte proporcionado en  
la estación de acoplamiento.



### 4.Fija la bomba con el depósito y el adaptador en el frasco

Confiéndole toda la bomba con un depósito y un adaptador conectado en el frasco verticalmente desde arriba, como se muestra en la imagen. El adaptador se encajará en el frasco con un clic audible.



### 5.Comience a llenar

Coloque la bomba en la estación de acoplamiento. La bomba debe mantenerse en posición vertical durante el período Llenado.



Presione **Sí** para iniciar el proceso de llenado. La unidad bombeará el medicamento del frasco al reservorio.

### 6.Retire y desechar el frasco

La bomba le avisará cuando el reservorio esté lleno. Asegúrese de que este es el caso y presione **Sí**.

Agarre el frasco en el adaptador y gire a la izquierda para retirar ambos del depósito.



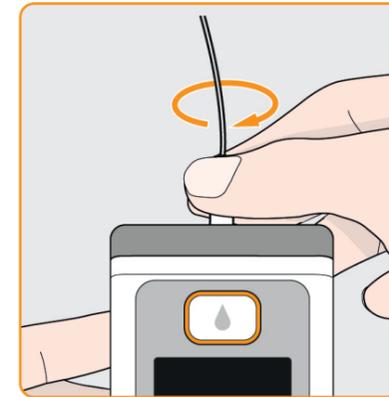
De acuerdo con las instrucciones del frasco

Si ahora desea continuar conectándose a un conjunto de infusión, presione **Sí, sí**

## Iv. Inicio y inicio de la infusión

### 1.Conecte el conjunto de infusión

Retire un nuevo conjunto de infusión del embalaje y Conectáelo con el reservorio de su bomba. Asegúrese de que la conexión esté bien apretada.

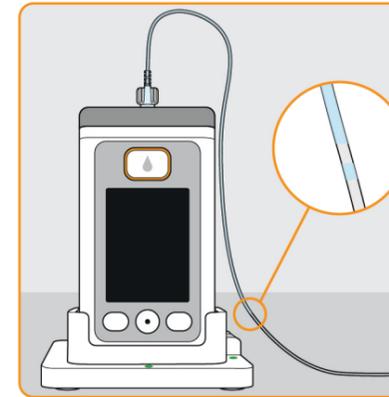


### 2.Coloque la bomba con el conjunto de infusión en la estación de acoplamiento

Incluso durante el inicio del conjunto de infusión, la bomba debe permanecer vertical siempre.

### 3.Inicie el proceso de cebado

Presione **Sí**. La unidad bombeará el medicamento del reservorio al conjunto de infusión.



Llevará unos segundos hasta que el líquido sea visible en el conjunto de infusión.

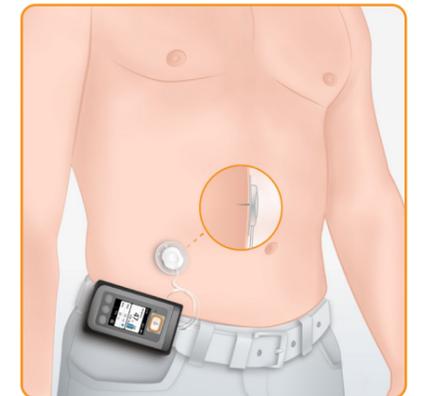
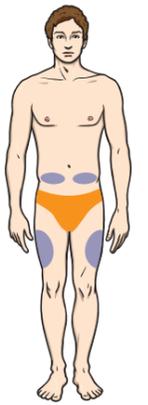
### 4.Preparar el lado de la punción

Las siguientes áreas son adecuadas para colocar el conjunto de infusión Subcutáneamente:

- cintura alrededor del mezon
- muslo exterior

Use una almohadilla o solución de desinfección. Desinfectar el sitio de punción. Entonces

- Tome un pliegue de la piel y la perfora con la aguja del catéter
- Presione la lámina adhesiva del catéter sobre la piel
- Quite el agarre del catéter (dependiendo del tipo de catéter) para soportar el tubo del catéter, y lo anule 1-3 veces con cinta adhesiva en su piel



### 5. Iniciar o detener la administración de medicamentos

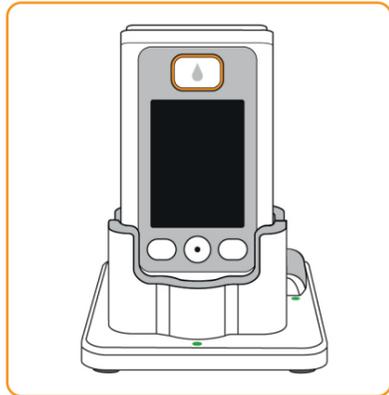
Para iniciar la prensa de **Comience** infusión. Puede usar teclas de función para comenzar y detener la entrega de medicamentos.

Para detener la prensa de **Infusión**.

## 6. Despegue y recargue la bomba

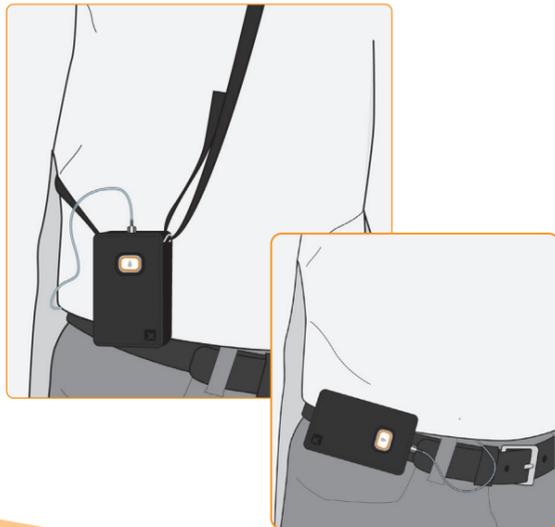
Retire el conjunto de infusión de su cuerpo. Luego desconectélo del embalse y descártelo.

Coloque la bomba en la estación de acoplamiento. El dispositivo se encuentra en la pantalla y confirma que la batería recargable en la bomba se está recargando con una notificación.



## 7. Cómo usar la bomba

Coloque la bomba en la caja de transporte. Puede usar la bomba con la correa ajustable alrededor del cuello, sobre el hombro o en la cintura.



## V. Configuración del dispositivo

### 1. Establecer la tasa básica

Puede programar el curso diario de la tasa base en hasta cinco períodos de tiempo libremente seleccionables (tiempo base).

Navegue a la configuración de entrega en el menú y seleccione el perfil básico. Presione hasta que se muestre el tiempo básico que desea cambiar. Presione y ingrese el código de liberación.

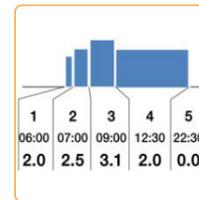
Confirme el límite del período de tiempo básico y presione para confirmar el tiempo de finalización.

Establezca la nueva tasa base y presione.

Presione para confirmar todos los demás tiempos basales uno por uno.

Después de que todos los períodos de tiempo se confirmen, la bomba le muestra todo el perfil en un diagrama.

| Basal profile |          |
|---------------|----------|
| 1             | 2        |
| Start         | 06:00 h  |
| End           | 15:00 h  |
| Basalrate     | 0.5 mg/h |



Se recomienda tomar nota de los valores de la configuración (consulte un ejemplo de la tabla de configuración de entrega en la siguiente página).

| Basal rate for basal time 1 | Start | End | Basal rate                    |
|-----------------------------|-------|-----|-------------------------------|
|                             | h     | h   | Comience Distribución de mg/h |
| Basal rate for basal time 2 | Start | End | Basal rate                    |
|                             | h     | h   | mg/h                          |
| Basal rate for basal time 3 | Start | End | Basal rate                    |
|                             | h     | h   | mg/h                          |
| Basal rate for basal time 4 | Start | End | Basal rate                    |
|                             | h     | h   | mg/h                          |
| Basal rate for basal time 5 | Start | End | Basal rate                    |
|                             | h     | h   | mg/h                          |

### 2. Establecimiento de la tasa de bolus

La configuración incluye

- la cantidad de bolus
- el número de boli permitido durante el día
- Peroid desactivado mínimo (tiempo de bloqueo)

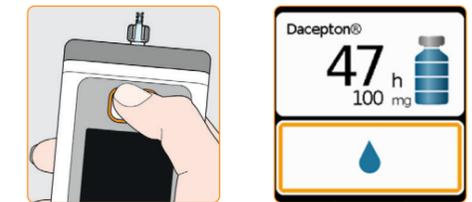
Navegue a la configuración de entrega en el menú y seleccione el bolus establecido. Presione y ingrese el código de liberación.

Establezca la configuración de bolus de la misma manera que la configuración inicial del dispositivo.

| Set bolus   |        |
|-------------|--------|
| Dose        | 2.3 mg |
| Boluses per | 5 day  |
| Lockout     | 60 min |

### 3. Entregar un bolus

Se proporciona un botón separado sobre la pantalla para entregar un bolus. El dispositivo muestra un mensaje correspondiente en la sección de texto de la pantalla.



La bomba indica la finalización con un aviso en la pantalla y el tono de señal "Bolo completado".

La función de bolus está desactivada

- si ha pasado demasiado poco tiempo desde el último bolus
- si ya se ha superado el número limitado de boluses
- si la cantidad de apomorfina disponible ya no es suficiente para un bolus

En estos casos, su bomba muestra el símbolo junto a la cantidad de bolus.

## Vi. Limpieza y almacenamiento

Cuando la bomba de pharma d-mine® se limpie :

- Limpe su bomba con un paño húmedo y el reservorio está conectado
- Si limpias la conexión de la bomba al reservorio, tenga cuidado de que no presione el acoplamiento flexible que se encuentra allí.
- preferiblemente usar agua o un agente de limpieza suave.
- No se pueden usar toallitas de limpieza médica con líquidos alcohólicos o sustancias relacionadas.

- Sin embargo, nunca use agentes de limpieza agresivos como acetona o ácido.

Almacene su bomba pharma d-mine® y sus accesorios en condiciones climáticas internas normales.

Deje de administrar medicamentos y quite la bomba como se describe en la sección 6. La caja de bomba D-mine® le ayuda a preparar todos los componentes cuando vuelva a poner la bomba en funcionamiento.

## Vii. símbolos y advertencias

|   |  |   |   |   |                          |
|---|--|---|---|---|--------------------------|
|    | Reservoir<br>Filling level 100%                                |    | Rechargeable battery<br>OK                      |    | Alarm                    |
|  | Reservoir<br>Filling level 75%                                 |  | Rechargeable battery<br>is being charged        |   | Notice                   |
|  | Reservoir<br>Filling level 50%                                 |  | Warning<br>Rechargeable battery<br>almost empty |  | Warning message          |
|  | Reservoir is filling<br>Filling level 25%                      |  | Alarm<br>Rechargeable battery<br>empty          |  | Unlock buttons           |
|  | Reservoir (not during filling)<br>Filling level below 25%      |  | Place pump upright in<br>docking station        |  | Bolus currently disabled |
|  | Alarm<br>Reservoir empty                                       |   |   |  | Ongoing delivery         |
|  | No reservoir<br>or<br>reservoir is filling<br>Filling level 0% |   |   |   |                          |

## Viii. especificaciones

|   |   |                   |                 |
|---|---|-------------------|-----------------|
| <b>Dimensions<br/>(with reservoir, without<br/>adapter)</b> | Length                                    | 114.3             | mm              |
|   | Width                                     | 61.4              | mm              |
|   | Thickness                                 | 29.9              | mm              |
| <b>Weight</b>   | Pump                                      | 140               | g               |
|   | Reservoir empty                           | 22                | g               |
| <b>Temperature</b>  | In operation                              | +5 to +40         | ° C             |
|   | Storage                                   | -25 to +70        | ° C             |
| <b>Air humidity</b>   | In operation                              | 15 to 93          | % rel.          |
|   | Storage                                   | up to 93          | % rel.          |
| <b>Atmospheric pressure</b>                                 | In operation                              | 70 to 106         | kPa (mbar)      |
|   | Storage                                   | n/a               | kPa (mbar)      |
| <b>Power supply</b>   | Rechargeable battery                      | Lithium polymer   | V               |
|   |   | 3.7<br>650<br>2.4 | mAh<br>Wh       |
| <b>Service life of a<br/>rechargeable battery</b>           | Typical operating time with one<br>charge | 7                 | days            |
|   | Number of charging cycles                 | 300               | cycles          |
| <b>History</b>  | View                                      | 3                 | days            |
|   |   | 15                | entries         |
|   | Readout                                   | 125<br>up to 625  | days<br>entries |

### ¿Alguna otra pregunta?

Si tiene alguna pregunta, llame a su línea de ayuda local.

Tu equipo de atención D-mine®.

**ABBREVIATED PRESCRIBING INFORMATION:** Dacepton 5 mg/ml Solution for infusion. **QUALITATIVE AND QUANTITATIVE COMPOSITION:** 1 ml contains 5 mg apomorphine hydrochloride hemihydrate, 20 ml contain 100 mg apomorphine hydrochloride hemihydrate. Excipient with known effect: Sodium metabisulphite (E223) 1 mg per ml, Sodium chloride 8 mg per ml. **PHARMACEUTICAL FORM:** Solution for infusion. Clear and colourless to slightly yellow solution, free from visible particles, pH of 3.3 – 4.0. Osmolality: 290 mOsm/kg. **THERAPEUTIC INDICATIONS:** Treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication. **POSLOGY AND METHOD OF ADMINISTRATION:** Selection of Patients suitable for Dacepton 5 mg/ml solution for infusion: Patients selected for treatment with Dacepton 5 mg/ml solution for infusion should be able to recognise the onset of their "off" symptoms and be capable of injecting themselves or else have a responsible carer able to inject for them when required. It is essential that the patient is established on domperidone, usually 20 mg three times daily, for at least two days prior to initiation of therapy. Apomorphine should be initiated in the controlled environment of a specialist clinic. The patient should be supervised by a physician experienced in the treatment of Parkinson's disease (e.g. neurologist). The patient's treatment with levodopa, with or without dopamine agonists, should be optimised before starting treatment with Dacepton 5 mg/ml solution for infusion. Adults: **METHOD OF ADMINISTRATION:** Dacepton 5 mg/ml solution for infusion is a pre-diluted vial intended for use without dilution for subcutaneous use and to be administered as a continuous subcutaneous infusion by minipump and/or syringe-driver. It is not intended to be used for intermittent injection. Apomorphine must not be used via the intravenous route. Do not use if the solution has turned green. The solution should be inspected visually prior to use. Only clear, colourless to slightly yellow and particle free solution should be used. **POSLOGY:** Continuous Infusion Patients who have shown a good "on" period response during the initiation stage of apomorphine therapy, but whose overall control remains unsatisfactory using intermittent injections, or who require many and frequent injections (more than 10 per day), may be commenced on or transferred to continuous subcutaneous infusion by minipump and/or syringe-driver as follows: The choice, of which minipump and / or syringe-driver to use, and the dosage settings required, will be determined by the physician in accordance with the particular needs of the patient. **DETERMINATION OF THRESHOLD DOSE:** The threshold dose for continuous infusion should be determined as follows: Continuous infusion is started at a rate of 1 mg apomorphine hydrochloride hemihydrate (0.2 ml) per hour then increased according to the individual response each day. Increases in the infusion rate should not exceed 0.5 mg at intervals of not less than 4 hours. Hourly infusion rates may range between 1 mg and 4 mg (0.2 ml and 0.8 ml), equivalent to 0.014-0.06 mg/kg/hour. Infusions should run for waking hours only. Unless the patient is experiencing severe night-time problems, 24 hour infusions are not advised. Tolerance to the therapy does not seem to occur as long as there is an overnight period without treatment of at least 4 hours. In any event, the infusion site should be changed every 12 hours. Patients may need to supplement their continuous infusion with intermittent bolus boosts, as necessary, and as directed by their physician. A reduction in dosage of other dopamine agonists may be considered during continuous infusion. **ESTABLISHMENT OF TREATMENT:** Alterations in dosage may be made according to the patient's response. The optimal dosage of apomorphine hydrochloride hemihydrate varies between individuals but, once established, remains relatively constant for each patient. **PRECAUTIONS ON CONTINUING TREATMENT:** The daily dose of Dacepton 5 mg/ml solution for infusion varies widely between patients, typically within the range of 3-30 mg. It is recommended that the total daily dose of apomorphine hydrochloride hemihydrate should not exceed 100 mg. In clinical studies it has usually been possible to make some reduction in the dose of levodopa; this effect varies considerably between patients and needs to be carefully managed by an experienced physician. Once treatment has been established, domperidone therapy may be gradually reduced in some patients but successfully eliminated only in a few, without any vomiting or hypotension. Paediatric population: Dacepton 5 mg/ml solution for infusion is contraindicated for children and adolescents under 18 years of age. Elderly: The elderly are well represented in the population of patients with Parkinson's disease and constitute a high proportion of those studied in clinical trials of apomorphine. The management of elderly patients treated with apomorphine has not differed from that of younger patients. However, extra caution is recommended during initiation of therapy in elderly patients because of the risk of postural hypotension. Renal impairment: A dose schedule similar to that recommended for adults, and the elderly, can be followed for patients with renal impairment. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. In patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency, Apomorphine hydrochloride hemihydrate treatment must not be administered to patients who have an "on" response to levodopa which is marred by severe dyskinesia or dystonia. Dacepton 5 mg/ml solution for infusion is contraindicated for children and adolescents under 18 years of age. Special warnings and precautions for use Apomorphine hydrochloride hemihydrate should be given with caution to patients with renal, pulmonary or cardiovascular disease and persons prone to nausea and vomiting. Extra caution is recommended during initiation of therapy in elderly and/or debilitated patients. Since apomorphine may produce hypotension, even when given with domperidone pre-treatment, care should be exercised in patients with pre-existing cardiac disease or in patients taking vasoactive medicinal products such as antihypertensives, and especially in patients with pre-existing postural hypotension. Since apomorphine, especially at high dose, may have the potential for QT prolongation, caution should be exercised when treating patients at risk for torsades de pointes arrhythmia. Apomorphine is associated with local subcutaneous effects. These can sometimes be reduced by the rotation of injection sites or possibly by the use of ultrasound (if available) in order to avoid areas of nodularity and induration. Haemolytic anaemia and thrombocytopenia have been reported in patients treated with apomorphine. Haematology tests should be undertaken at regular intervals as with levodopa, when given concomitantly with apomorphine. Caution is advised when combining apomorphine with other medicinal products, especially those with a narrow therapeutic range. Neuropsychiatric problems co-exist in many patients with advanced Parkinson's disease. There is evidence that for some patients neuropsychiatric disturbances may be exacerbated by apomorphine. Special care should be exercised when apomorphine is used in these patients. Apomorphine has been associated with somnolence, and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with apomorphine. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore, a reduction of dosage or termination of therapy may be considered. Impulse control disorders: Patients should be regularly monitored for the development of impulse control disorders. Patients and carers should be made aware that behavioural symptoms of impulse control disorders including pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists including apomorphine. Dose reduction/tapered discontinuation should be considered if such symptoms develop. Dopamine dysregulation Syndrome (DDS) is an addictive disorder resulting in excessive use of the product seen in some patients treated with apomorphine. Before initiation of treatment, patients and caregivers should be warned of the potential risk of developing DDS. Dacepton 5 mg/ml solution for infusion contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm. Dacepton 5 mg/ml contains 3.4 mg sodium per ml. To be taken into consideration by patients on a controlled sodium diet. Interaction with other medicinal products and other forms of interaction: Patients selected for treatment with apomorphine hydrochloride hemihydrate are almost certain to be taking concomitant medications for their Parkinson's disease. In the initial stages of apomorphine hydrochloride hemihydrate therapy, the patient should be monitored for unusual side-effects or signs of potentiation of effect. Neuroleptic medicinal products may have an antagonistic effect if used with apomorphine. There is a potential interaction between doxapine and apomorphine, however clozapine may also be used to reduce the symptoms of neuropsychiatric complications. If neuroleptic medicinal products have to be used in patients with Parkinson's disease treated by dopamine agonists, a gradual reduction in apomorphine dose may be considered when administration is by minipump and/or syringe-driver (symptoms suggestive of neuroleptic malignant syndrome have been reported rarely with abrupt withdrawal of dopaminergic therapy). The possible effects of apomorphine on the plasma concentrations of other medicinal products have not been studied. Therefore caution is advised when combining apomorphine with other medicinal products, especially those with a narrow therapeutic range. Antihypertensive and Cardiac Active Medicinal Products: Even when co-administered with domperidone, apomorphine may potentiate the antihypertensive effects of these medicinal products. It is recommended to avoid the administration of apomorphine with other drugs known to prolong the QT interval. Concomitant use of apomorphine with ondansetron may lead to severe hypotension and loss of consciousness and is therefore contraindicated (see section 4.3). Such effects might also occur with other 5-HT<sub>3</sub> antagonists. Fertility, pregnancy and lactation: There is no experience of apomorphine usage in pregnant women. Animal reproduction studies do not indicate any teratogenic effects, but doses given to rats which are toxic to the mother can lead to failure to breathe in the newborn. The potential risk for humans is unknown. Dacepton 5 mg/ml solution for infusion should not be used during pregnancy unless clearly necessary. It is not known whether apomorphine is excreted in breast milk. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with Dacepton 5 mg/ml solution for infusion should be made taking into account the benefit of breast-feeding to the child and the benefit of Dacepton 5 mg/ml solution for infusion to the woman. Effects on ability to drive and use machines: Apomorphine hydrochloride hemihydrate has minor or moderate influence on the ability to drive and use machines. Patients being treated with apomorphine and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities (e.g. operating machines) where impaired alertness may put themselves or others at risk of serious injury or death until such recurrent episodes and somnolence have resolved. **UNDESIRABLE EFFECTS:** Very common:  $\geq 1/10$ , common:  $\geq 1/100$  to  $< 1/10$ , uncommon:  $\geq 1/1,000$  to  $< 1/100$ , rare:  $\geq 1/10,000$  to  $< 1/1,000$ , very rare:  $< 1/10,000$ , Not known: (cannot be estimated from the available data). Blood and lymphatic system disorders: Uncommon: Haemolytic anaemia and thrombocytopenia have been reported in patients treated with apomorphine. Rare: Eosinophilia has rarely occurred during treatment with apomorphine hydrochloride hemihydrate. Immune system disorders: Rare: Due to the presence of sodium metabisulphite, allergic reactions (including anaphylaxis and bronchospasm) may occur. Psychiatric disorders: Common: Neuropsychiatric disturbances are common in parkinsonian patients. Dacepton 5 mg/ml solution for infusion should be used with special caution in these patients. Neuropsychiatric disturbances (including transient mild confusion and visual hallucinations) have occurred during apomorphine hydrochloride hemihydrate therapy. Not known: Impulse control Trastornos: los pacientes que reciben agonistas de la dopamina, incluida la apomorfina, pueden producir juegos de azar patológicos, aumento de la libido, hipersexualidad, gasto o compra compulsivo, comida excesiva y comida compulsiva. Agresión, agitación. Trastornos del sueño: los pacientes tratados con cada dosis de hidrocloreuro de apomorfina hemihidratado al comienzo del tratamiento; Esto generalmente se resuelve en las primeras semanas. La apomorfina está asociada con la somnolencia. También se han informado mareos/ caídas. El paciente puede causar discinesias durante el período de "encendido", que puede ser grave en algunos casos y en algunos pacientes puede causar el cese del tratamiento. La apomorfina se ha asociado con episodios repentinos de sueño, síncope y dolor de cabeza. **Precautions for use:** Apomorphine is usually transient: Respiratory, thoracic and distal disorders Common: Yawning has been reported during apomorphine therapy. Uncommon: Breathing difficulties have been reported. Gastrointestinal disorders: Common: Nausea and vomiting, particularly when apomorphine treatment is first initiated, usually as a result of the omission of domperidone. Skin and subcutaneous tissue disorders: Uncommon: Local and generalised rashes have been reported, (e.g. disorders and administration site conditions): Very common: Most patients experience injection site reactions, particularly with continuous use. These may include subcutaneous nodules, induration, erythema, tenderness and panniculitis. Various other local reactions (such as irritation, itching, bruising and pain) may also occur. Uncommon: Injection site necrosis and ulceration have been reported. Not Known: Peripheral oedema has been reported. Investigations Uncommon: Positive Coombs' tests have been reported for patients receiving apomorphine. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. Overdose: There is little clinical experience of overdose with apomorphine by this route of administration. Symptoms of overdose may be treated empirically as suggested: Excessive emesis may be treated with domperidone. Respiratory depression may be treated with naloxone. Hypotension: appropriate measures should be taken, e.g. raising the foot of the bed. Bradycardia may be treated with atropine. **PHARMACODYNAMIC PROPERTIES:** Pharmacotherapeutic group: Anti-Parkinson drugs, dopamine agonists, ATC code: N04B C07. Mechanism of action: Apomorphine is a direct stimulant of dopamine receptors and while possessing both D1 and D2 receptor agonist properties does not share transport or metabolic pathways with levodopa. Although in intact experimental animals, administration of apomorphine suppresses the rate of firing of nigro-striatal cells and in low dose has been found to produce a reduction in locomotor activity (thought to represent pre-synaptic inhibition of endogenous dopamine release) its actions on parkinsonian motor disability are likely to be mediated at post-synaptic receptor sites. This biphasic effect is also seen in humans. Pharmacokinetic properties: After subcutaneous injection of apomorphine its fate can be described by a two-compartment model, with a distribution half-life of 5 ( $\pm 1.1$ ) minutes and an elimination half-life of 33 ( $\pm 3.9$ ) minutes. Clinical response correlates well with levels of apomorphine in the cerebrospinal fluid; the active substance distribution being best described by a two-compartment model. Apomorphine is rapidly and completely absorbed from subcutaneous tissue, correlating with the rapid onset of clinical effects (4-12 minutes), and that the brief duration of clinical action of the active substance (about 1 hour) is explained by its rapid clearance. The metabolism of apomorphine is by glucuronidation and sulphonation to at least ten per cent of the total; other pathways have not been described. **PRECLINICAL SAFETY DATA:** Repeat dose subcutaneous toxicity studies reveal no special hazard for humans, beyond the information included in other sections of the SmPc. In vitro genotoxicity studies demonstrated mutagenic and clastogenic effects, most likely due to products formed by oxidation of apomorphine. However, apomorphine was not genotoxic in the in vivo studies performed. The effect of apomorphine on reproduction has been investigated in rats. Apomorphine was not teratogenic in this species, but it was noted that doses which are toxic to the mother can cause loss of maternal care and failure to breathe in the newborn. No carcinogenicity studies have been performed. **LIST OF EXCIPIENTS:** Sodium metabisulphite (E223), Sodium chloride, Hydrochloric acid (for pH-adjustment), water for injections. **Incompatibilities:** In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. **SHELF LIFE:** Unopened: 30 months. After opening and filling the drug product in syringes attached with infusion sets: chemical and physical in-use stability has been demonstrated for 7 days at 25 °C. From a microbiological point of view, unless the method of opening and further handling precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Single use only. Discard any unused contents. Special precautions for storage: Keep the vials in the outer carton in order to protect from light. Do not refrigerate or freeze. **NATURE AND CONTENTS OF CONTAINER:** Clear glass vials, type I with bromobutyl rubber stopper and a flip-off cap, containing 20 ml solution for infusion, in packs of 1 or 5 vials. Bundle packs: 5 x 1, 10 x 1, 30 x 1, 2 x 5 and 6 x 5. Not all pack sizes may be marketed. Special precautions for disposal and other handling: Do not use if the solution has turned green. The solution should be inspected visually prior to use. Only clear and colourless to slightly yellow solutions without particles in undamaged containers should be used. For single use only. Any unused medicinal product or waste material should be disposed in accordance with local requirements. Continuous infusion and the use of a minipump and/or syringe-driver The choice of which minipump and/or syringe-driver to use, and the dosage settings required, will be determined by the physician in accordance with the particular needs of the patient. **MARKETING AUTHORISATION HOLDER:** EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach, Österreich. **MARKETING AUTHORISATION NUMBER:** AT/H/0364/002/DC. Legal Category: POM. Date of last revision: October 2023.