PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: **S4**

TACYPHEN, 10 mg/ml solution for injection

Phenylephrine hydrochloride.

Sugar free.

Read all of this leaflet carefully before you are given TACYPHEN:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

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

1. What TACYPHEN is and what it is used for:

TACYPHEN contains the active ingredient called phenylephrine. TACYPHEN raises blood pressure by making the blood vessels narrower (also called constricting).

TACYPHEN is used to treat low blood pressure, which may be caused by circulatory failure, spinal anaesthesia or septic shock.

2. What you need to know before you are given TACYPHEN:

TACYPHEN should not be administered to you:

- if you are hypersensitive to phenylephrine hydrochloride or any of the other ingredients of TACYPHEN (listed in **section 6**)
- if you are taking Monoamine Oxidase Inhibitors (MAOIs, used to treat depression) or have taken them in the last 14 days
- if you suffer from severe uncontrolled high blood pressure
- if you have a severe overactive thyroid
- if you have any severe heart problems or disease, including dysrhythmias or angina
- if you have a severe disease of your blood vessels, such as arteriosclerosis or aneurysms
- paediatric use.

Warnings and precautions:

Tell your doctor or healthcare provider before being given the injection:

Take special care with TACYPHEN:

- if you have any heart problems or disease, including dysrhythmias or angina
- if you have a disease of your blood vessels, such as arteriosclerosis or aneurysms
- if you have hyperthyroidism (see **section 2**)
- if you have a sulphite-sensitivity
- if you are in septic shock
- if you have diabetes mellitus
- if you have closed-angle glaucoma (increased pressure in the eye)
- if you are pregnant or breastfeeding your infant.
- if you suffer from prostatic enlargement
- paediatric use.

Other medicines and TACYPHEN:

Always tell your healthcare provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
In particular, tell your doctor or nurse if you are taking any of the following:

- monoamine oxidase inhibitors medicine prescribed for the treatment of depression
- tricyclic antidepressants
- lithium carbonate, a medicine used for depression or aggression
- atomoxetine used to treat attention-deficit hyperactivity disorder (ADHD)
- prazosin, doxazosin used to treat high blood pressure or symptoms of an enlarged prostate
- medicines used to treat high blood pressure
- medicines known as alpha blockers (used to treat Raynaud's syndrome or tumour of the adrenal gland) or beta blockers (used to treat heart conditions or reduce blood pressure)
- haloperidol used to treat mental illness
- clonidine used to treat high blood pressure
- granisetron used to prevent nausea and vomiting
- medicines used to treat heart conditions including cardiac glycosides or quinidine
- atropine or other antimuscarinics used to treat certain types of nerve conditions
- TACYPHEN may interact with some medicines used as general anaesthetics such as halogenated anaesthetics, but your doctor will be fully prepared to deal with this should it occur.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before being given TACYPHEN.
You should not receive TACYPHEN if you are pregnant or breastfeeding your baby.

Driving and using machines:

No adverse effects on the ability to drive or use machines are known.
It is not always possible to predict to what extent TACYPHEN may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which TACYPHEN affects you.

3. How TACYPHEN will be administered:
Do not share medicines prescribed for you with any other person.
TACYPHEN will be given to you by a person who is qualified to do so.
You will normally be given TACYPHEN in a hospital or clinic.
TACYPHEN will be diluted and given by slow injection or infusion (drip) into a vein.

If you use more TACYPHEN than you should:
Since a healthcare provider will administer TACYPHEN he/she will control the dosage. However, in the event of over dosage your doctor will manage the over dosage.

If you forget to use TACYPHEN:
Since a healthcare provider will administer TACYPHEN, it is unlikely that the dose will be missed.

4. Possible side effects:
TACYPHEN can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TACYPHEN, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor or healthcare professional immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TACYPHEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- an increase in blood pressure with headache and vomiting, which may cause bleeding in the brain or fluid in the lungs
- a change in your heart rate (speeding up, slowing down or cessation, palpitations)
- an irregular heartbeat (dysrhythmias)
- chest pain or pain due to angina

- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache.

Less frequent side effects:

- nervousness
- difficulty sleeping
- feeling anxious
- feeling excited, agitated
- feeling confused
- an abnormal sensation, typically tingling or pricking
- shaking
- angle-closure glaucoma (when pressure rises quickly inside the eyes)
- excessive dilation of the pupil
- high blood pressure or low blood pressure
- flushing
- sweating
- paleness
- goose bumps
- nausea, vomiting
- excessive production of saliva
- difficulty in passing urine or urine retention
- muscle weakness.

Side effects with unknown frequency:

- tissue damage at the site of the injection
- accidental infiltration of a medicine into the surrounding IV site
- excessive sweating
- altered metabolism including glucose metabolism.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TACYPHEN.

5. How to store TACYPHEN:

Store all medicine out of reach of children.

Store at or below 25 °C.

Store in the original package.

Do not use TACYPHEN if you notice foreign particles in the solution or if the solution is not clear and colourless.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What TACYPHEN contains:

The active ingredient is phenylephrine hydrochloride 10 mg per ml.

The other ingredients are hydrochloric acid, sodium hydroxide and water for injection.

What TACYPHEN looks like and contents of the pack:

TACYPHEN is a clear, colourless sterile solution for injection. TACYPHEN is packaged in amber-coloured glass vials (Type I). The ampoules are placed in trays holding 5 or 10 ampoules; these are packed into a cardboard packet with the corresponding professional information.

Holder of Certificate of Registration:

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PASIËNTINLIGTINGSBLAD:

SKEDULERINGSTATUS: S4

TACYPHEN, 10 mg/ml oplossing vir inspuiting

Fenielefrienhidrochloried.

Suikervry.

Lees hierdie hele blad noukeurig deur voordat TACYPHEN aan u gegee word:

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

Wat in hierdie blad is:

1. Wat TACYPHEN is en waarvoor dit gebruik word
2. Wat u moet weet voordat u TACYPHEN kry
3. Hoe om TACYPHEN te gebruik
4. Moontlike newe-effekte
5. Hoe om TACYPHEN te bêre
6. Inhoud van die pak en ander inligting

1. Wat TACYPHEN is en waarvoor dit gebruik word:

TACYPHEN bevat die aktiewe bestanddeel genaamd fenielefrien. TACYPHEN verhoog die bloeddruk deur die bloedvate nouer te maak (ook konstriksie genoem).

TACYPHEN word gebruik om lae bloeddruk te behandel, wat veroorsaak kan word deur sirkulatoriese versaking, spinale narkose of septiese skok.

2. Wat u moet weet voordat u TACYPHEN kry:

TACYPHEN moet nie aan u gegee word nie:

- as u hipersensitief vir fenielefrienhidrochloried of vir enige van die ander bestanddele (gelys in **afdeling 6**) van TACYPHEN is
- as u monoamienoksidaseremmers (MAOR's) gebruik (om depressie te behandel), of dit in die afgelope 14 dae gedrink het
- as u erge onbeheerde hoë bloeddruk het
- as u 'n erg ooraktiewe skildklier het
- as u erge hartprobleme of -siektes het, waaronder disritimie of angina
- as u 'n erge siekte in u bloedvate het, soos arteriosklerose of aneurismes
- pediatriese gebruik.

Waarskuwings en voorsorgmaatreëls:

Sê voordat u die inspuiting kry vir u dokter of gesondheidsorgverskaffer:

Wees veral versigtig met TACYPHEN:

- as u enige hartprobleme of -siektes het, waaronder disritimie of angina
- as u ’n siekte in u bloedvate het, soos arteriosklerose of aneurismes
- as u hipertireose het (kyk **afdeling 2**)
- as u ’n sensitiwiteit vir sulfiet het
- as u in septiese skok is
- as u diabetes mellitus het
- as u nouhoekgloukoom het (hoë druk in die oë)
- as u swanger is of u baba borsvoed
- as u ’n vergote prostaat het
- met pediatriese gebruik.

Ander medisyne en TACYPHEN:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

Sê veral vir u dokter of verpleegkundige as u enige van die volgende gebruik:

- monoamienoksidaseremmers wat vir die behandeling van depressie voorgeskryf word
- trisikliese antidepressante
- litiumkarbonaat, medisyne wat vir depressie of aggressie gebruik word
- atomoksetien wat gebruik word om aandagafleibaarheid en hiperaktiwiteitsversteuring (ADHD) te behandel
- prasosien, doksasosien om hoë bloeddruk of simptome van ’n vergrote prostaat te behandel
- medisyne vir behandeling van hoë bloeddruk
- medisyne bekend as alfa-blokkers (wat gebruik word om Raynaud se sindroom of tumor van die byniere te behandel) of beta-blokkers (wat gebruik word om harttoestande te behandel of om bloeddruk te verlaag)
- haloperidol vir die behandeling van geestesongesteldheid
- klonidien vir behandeling van hoë bloeddruk
- granisetron, medisyne om naarheid en braking te behandel
- medisyne wat gebruik word om harttoestande te behandel, waaronder hartglikosiede of kinidien
- atropien of ander antimuskarinika wat gebruik word om sekere soorte senutoestande te behandel
- TACYPHEN kan ’n interaksie hê met sekere medisyne wat vir algemene narkose gebruik word, soos gehalogeneerde anestetika, maar u dokter is ten volle voorberei om dit te hanteer indien dit sou voorkom.

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om ’n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer om advies raadpleeg voordat u TACYPHEN kry.

U moet nie TACYPHEN kry as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjiene:
Geen nadelige effekte op die vermoë om ’n voertuig te bestuur of masjiene te hanteer is bekend nie.
Dit is nie altyd moontlik om te voorspel tot watter mate TACYPHEN met u daaglikse aktiwiteite kan inmeng nie. U moet sorg dat u nie ’n voertuig bestuur of masjiene hanteer nie, totdat u weet hoe TACYPHEN u beïnvloed.

3. Hoe TACYPHEN gegee sal word:
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
TACYPHEN sal aan u gegee word deur ’n persoon wat bevoeg is om dit te doen.
U sal TACYPHEN normaalweg in ’n hospitaal of kliniek kry.
TACYPHEN word deur stadige inspuiting of infusie (druppel) in ’n aar gegee.

As u meer TACYPHEN gebruik het as wat u moes:
Omdat ’n gesondheidsorgverskaffer TACYPHEN sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

As u vergeet om TACYPHEN te gebruik:
Aangesien ’n gesondheidsorgverskaffer TACYPHEN sal gee, is dit onwaarskynlik dat ’n dosis oorgeslaan sal word.

4. Moontlike newe-effekte:
TACYPHEN kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir hierdie medisyne aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u TACYPHEN kry, moet u u gesondheidsorgverskaffer om advies raadpleeg.

As enige van die volgende voorkom, moet u dadelik vir u dokter of gesondheidspraktisyn sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u ’n ernstige reaksie op TACYPHEN het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- styging in bloeddruk met hoofpyn en braking, wat bloeding in die brein of vloeistof in die longe kan veroorsaak
- ’n verandering in u hartklop (vinniger, stadiger of staking, hartkloppings)
- ’n onreëlmatige hartklop (disritmie)
- pyn op die bors of pyn as gevolg van angina
- probleme met asemhaling.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- hoofpyn.

Newe-effekte wat minder dikwels voorkom:

- senuagtigheid
- probleme om te slaap
- voel angstig
- voel opgewonde, opgewek
- voel verward
- ’n abnormale gevoel, tipies tintelend of prikkelend
- bewerasie
- nouhoekgloukoom (as die druk in die oë vinnig styg)
- oormatige vergroting van die pupille
- hoë of lae bloeddruk
- blosing
- sweet
- bleekheid
- hoendervleis
- naarheid, braking
- oormatige produksie van speeksel
- probleme met urinering of urienretensie
- spierswakheid.

Newe-effekte met onbekende frekwensie:

- weefselskade by die plek van die inspuiting
- onopsetlike infiltrasie van medisyne in die omgewing van die IV-inspuitplek
- oormatige sweet
- veranderde metabolisme waaronder glukosemetabolisme.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte:
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SAHPRA aanmeld via die vorm vir die aanmeld van nadelige geneesmiddelreaksies, naamlik **6.04 Adverse Drug Reaction Reporting Form** wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TACYPHEN te gee.

5. Hoe om TACYPHEN te bêre:
Hou alle medisyne buite bereik van kinders.
Bêre by of onder 25 °C.
Bêre in die oorspronklike verpakking.
Moenie TACYPHEN gebruik as u vreemde deeltjies in die oplossing sien of as die oplossing nie helder en kleurloos is nie.
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting:
Wat TACYPHEN bevat:
Die aktiewe bestanddeel is 10 mg fenielefrienhidrochloried per ml.
Die ander bestanddele is soutsuur, natriumhidroksied en water vir inspuiting.

Hoe TACYPHEN lyk en die inhoud van die pakkie:
TACYPHEN is ’n helder, kleurlose steriele oplossing vir inspuiting. TACYPHEN is verpak in amberkleurige glasflessies (Tipe I). Die ampules is in bakkies wat 5 of 10 ampules bevat; dit is saam met die ooreenstemmende voubiljet in ’n karton verpak.

Houer van die registrasiesertifikaat:
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