Takipril®
Clinical Application

At a glance

Your overview pocket card

The handy Takipril® pocket card is an easy to stow companion, delivering all the important information about procedure details and dosage at a single glance.

B|BRAUN
SHARING EXPERTISE

2 % Hyperbaric Prilocaine HCl (Takipril®)

Indication: Outpatients or inpatients for Spinal Anesthesia with surgery time ≤ 90 min

Type of surgical procedure [1]	Drug dose (ml)	Drug dose (mg)
ORTHOPEDIC		
Knee & foot surgery	2-2.5	40 - 50
Hip & thigh surgery	2.5 -3	50 - 60
GENERAL SURGERY		
Inguinal hernia repair	2.5 -3	50 - 60
Perianal surgery	1-1.5	20 - 30
GYNAECOLOGY		
External genital surgery	1-1.5	20 - 30
Suction curettage	2	40
UROLOGY		
Transurethral resection (TUR)	2.5-3	50 - 60

For patients up to 170 cm in height are more likely to be operated with lower doses. Higher doses are recommended for patients taller than 180 cm.

If saddle block is not required, the patient should lay back onto the bed as quickly as possible. The spread of the spinal anesthetics is then controlled with tilting of the operating table.

1. Dosage recommendations according to Prof. Dr. Wulf, chairman of the department of anaesthesiology from the University Hospital of Marburg in Germany, Feb. 2018.

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Product Information & Literature

Takipril® 20 mg/ml solution for injection

COMPOSITION
1 ml — 20 mg prilocaine hydrochloride
1 ampoule with 5 ml — 100 mg prilocaine hydrochloride

Excipients:
Each 5 ml ampoule contains 0.043 mg sodium.
Glucose anhydrous, sodium hydroxide 1N (for pH adjustment), water for injection.

THERAPEUTIC INDICATIONS
Takipril® is indicated in adults for spinal anaesthesia in short-term surgical procedures.

CONTRAINDICATIONS
Takipril® must not be used in patients wit hypersensitivity to prilocaine hydrochloride, other amide-type local anaesthetics or to any of the excipients, serious problems with cardiac conduction, severe anaemia, decompensated cardiac insufficiency, cardiogenic and hypovolemic shock, congenital or acquired methemoglobinemia, concomitant anticoagulant therapy general and specific contraindications for the technique of subarachnoid anaesthesia.

The use of Takipril® in children younger than 6 months is contraindicated due to a higher risk of developing methemoglobinemia. The intravascular injection of Takipril® 20 mg/ml hyperbar is contraindicated. Takipril® must not be injected into infected areas.

Undesirable effects
The possible undesirable effects due to the use of Takipril are generally similar to the undesirable effects of other local anaesthetics for spinal anaesthesia from the amide group. The undesirable effects induced by the medicinal product are difficult to distinguish from the physiological effects of the nerve block (e.g. reduction in arterial pressure, bradycardia, temporary urine retention), from direct effects (e.g. spinal hematoma) or the indirect effects (e.g. meningitis) of the injection or from the effects due to the loss of cerebrospinal liquid (e.g. post-spinal headache).

Undesirable effects are listed according to their frequencies as follows:
Very common: (≥ 1/10)
Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1000 to < 1/100)
Rare: (≥ 1/10000 to < 1/1000)

Blood and lymphatic system disorders
Rare: Methemoglobinemia, Cyanosis.
Immune system disorders
Rare: Anaphylactic shock, Anaphylactic reactions, Allergic reactions, Itching.
Nervous system Disorders
Common: Paresthesia, Dizziness;
Uncommon: Signs and symptoms of CNS toxicity (convulsions, circumoral paresthesia, loss of consciousness, shaking, feeling of numbness affecting the tongue, speech problems, hearing problems, tinnitus, visual problems).
Rare: Arachnoiditis, Neuropathy, Lesions of peripheral nerves.
Eye disorders
Rare: Diplopia.
Cardiac disorders
Uncommon: Bradycardia.
Rare: Cardiac arrest, Arrhythmia.
Vascular disorders
Very common: Hypotension.
Uncommon: Hypertension.
Respiratory, thoracic and mediastinal disorders
Rare: Respiratory depression.
Musculoskeletal and connective tissue disorders
Uncommon: Back pain, temporary muscle weakness.
Gastrointestinal disorders
Very common: Nausea.
Common: Vomiting.

The signs of intoxication from local anaesthetics are similar for any injected preparation, both in the way in which they manifest, and in their treatment.

In spite of the demonstrated high clinical tolerability of Takipril®, undesirable toxic effects cannot be excluded in the presence of plasma levels above a critical threshold. These undesirable effects mainly manifest as symptoms affecting the central nervous and cardiovascular system.

The most effective prophylactic measures are scrupulous compliance with the recommended posology for Takipril®, with it being essential for the doctor to check its action (visual and verbal contact with the patient), as well as careful aspiration prior to injecting the solution.

Mild undesirable effects (feeling dizzy or dazed) can be attributed to moderate overdose and generally resolve rapidly after reducing the dose or halting administration of Takipril®.

Serious undesirable effects are attributable to significant overdose and/or accidental injection of local anaesthetic into a blood vessel. They manifest as symptoms affecting the central nervous system (restlessness, speech problems, disorientation, dizziness, muscle contractions, cramps, vomiting, loss of consciousness, respiratory arrest and mydriasis) and the cardiocirculatory system (raised arterial pressure and pulse frequency, arrhythmia, drop in arterial pressure, asystole) following irritation and/or depression of the cerebral cortex and the cerebral marrow.

In addition, following inhibition or block of the cardiac conduction system, cardiac frequency may slow down and myocardial depression may occur.

Any problems relating to metabolism (liver) or excretion (kidney) of Takipril® should also be considered as other possible causes of undesirable effects.

WARNINGS
Keep out of the sight and reach of children.

Directions for proper use:

5 ml ampoules of solution for injection are exclusively single-use. Any remaining product must be disposed of.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 04/2014

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Literature

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B|BRAUN
SHARING EXPERTISE

FOR SURGERIES UP TO 90 MINUTES [1]

PRESCRIPTION | PATIENT ACCESS | PREPARATION | APPLICATION | DISCHARGE MANAGEMENT

Takipril®
2 % Hyperbaric Prilocaine HCl

Fast track Spinal Anesthesia

Short-Acting Spinal Anesthesia

With Takipril® 2 % Hyperbaric Prilocaine HCl

Spinal Anesthesia is a reliable technique for regional surgery on the lower half of the body. The choice of local anesthetics is the key to improve Spinal Anesthesia.

Takipril® vs. Bupivacaine
Shorter duration of action.

Spinal block characteristics [2]	Bupivacaine 0.5 %	Takipril®
Onset time of sensory block T12 (min)	5 (3)	4 (8)
Regression of sensory block S1 (min)	360 (60)	240 (90)
Onset time of maximum motor block (min)	10 (10)	10 (10)
Regression of motor block (Bromage 0) (min)	210 (90)	135 (90)

Median (quartile distance) values

Unilateral Anaesthesia
The injection of small doses of Takipril® 2 % Hyperbaric Prilocaine HCl can allow to restrict the block mostly at one side, helping to reduce the effects of sympathetic blockade and to improve the spinal block recovery profile (see Fig. 1).

Neural block characteristics [3]	Takipril® Unilateral	Takipril® Bilateral
Sensory block resolution on operated side (min)	156±30	158±26
Motor block resolution on operated side (min)	115±26	108±24
Sensory block resolution on non-operated side (min)	120±47	158±26
Motor block resolution on non-operated side (min)	64±48	108±24
Time to first voiding (min)	220±47	249±51

Mean +/- standard deviation

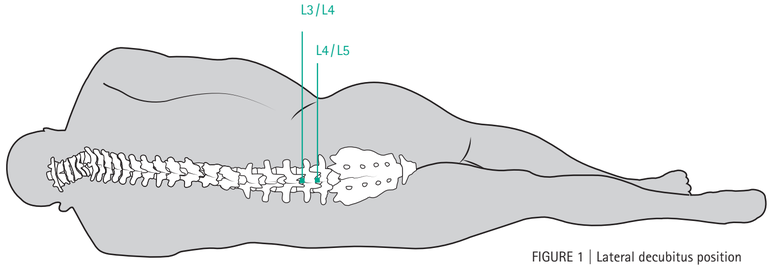
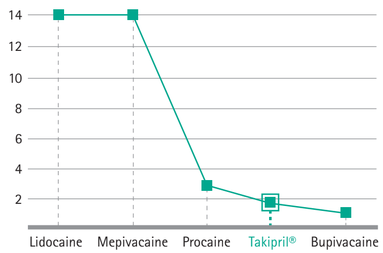


FIGURE 1 | Lateral decubitus position

2 % Hyperbaric Prilocaine HCl
Shorter duration of action offers advantages specifically for outpatient operations. [8]

Reliable and safe
Due to its block profile and the lower incidence of TNS Takipril® is a good alternative for short surgery (up to 90 min).

INCIDENCE OF TNS IN % [4]

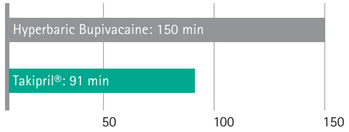


YOUR BENEFITS AT A GLANCE
- Faster than Hyperbaric Bupivacaine [2]
  - Faster regression of motor block
  - Faster time to first spontaneous voiding
  - Faster to discharge home
- Hyperbaric solution: Enable Unilateral Anesthesia which is faster than Bilateral Anesthesia
- Low incidence of urinary retention [5, 6]
- Hemodynamically stable [5, 7]

Shorter Recovery Room and Faster Discharge

Save money by significantly reducing recovery room time & discharge time
The time spent in recovery room and the time till discharge are significant determinants of operating theatre fees. Sensitivity analysis reveals cost savings per patient for Takipril®: 11.64 euros due to the shorter recovery room time and 64.76 euros for the time until spontaneous voiding. [8]

TIME SPENT IN RECOVERY ROOM [2]



TIME TILL DISCHARGE [2]