Drug Information Sheet("Kusuri-no-Shiori")

External

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The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: TULOBUTEROL TAPE 0.5 [OHARA]

Active ingredient: Tulobuterol

Dosage form: translucent and colorless tape (16 mm \times 16 mm)

Print on wrapping:(face): ツロブテロールテープ 0.5「オーハラ」, TULOBUTEROL

TAPE 0.5 OHARA, 0.5 mg, OH-144

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Effects of this medicine

This medicine makes breathing easier by stimulating β_2 receptors in the bronchial smooth muscles and dilating the bronchi

It is usually used to improve various symptoms including respiratory distress caused by bronchial asthma, acute bronchitis, chronic bronchitis and emphysema.

Before using this medicine, be sure to tell your doctor and pharmacist

- •If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you have hyperparathyroidism, hypertension, heart disease, diabetes mellitus or atopic dermatitis.
- •If you are pregnant or breastfeeding.
- •If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is<
- to be written by a healthcare professional>>
- •In general, for adults and children over 9 years, apply 2 mg of the active ingredient at a time to the chest, back or upper arms once a day. For children between 6 months to 2 years, apply 0.5 mg of the active ingredient at a time to the chest, back or upper arms once a day. For children between 3 to 8 years, apply 1 mg of the active ingredient at a time, to the chest, back or upper arms once a day. This medicine contains 0.5 mg of the active ingredient in each tape. Strictly follow the instructions.
- ·Wipe and clean the application site before applying the tape.
- •Change the application site every time to avoid stimulation of skin.
- ·Apply this medicine to a site where children cannot touch, since they might remove the tape.
- If you miss a dose, apply the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never apply two doses at one time.
- · If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include tremor, cardiac palpitation, itching sensation on application site, redness, eruption of skin, rash and hives. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- •respiratory distress, generalized flushing, hives [anaphylactoid symptoms]
- •paralysis of limbs, respiratory distress, conscious disorder [serious reduction in serum potassium level]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- •Keep out of the reach of children. Store away from light, heat and moisture.
- •Keep this medicine in the pouch and take it out of the pouch just before use
- ·Discard the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.