133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

29 June 2023

s 9(2)(a)

[redacted] [redacted]
Ref: H2023026446, H2023027281

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your requests under the Official Information Act 1982 (the Act) to Manatū Haoura (the Ministry of Health) on 2 June and 20 June 2023. I have consolidated the responses for these requests for convenience. You requested:

> *"I wish to request the following information regarding the medicine Sandrena, Transdermal gel, 0.1 % estradiol (registration now lapsed).*
>
> *Please provide a copy of the last primary and secondary labelling (including pack insert and tertiary labelling if applicable) approved by Medsafe in a CMN or notified in a SACN. If there has been no labelling CMN or SACN since the original NMA, please provide the labelling which was approved in the NMA.*
>
> *Please provide a copy of the last data sheet which was approved in a CMN or notified in a SACN.*
>
> *If there has been no data sheet CMN or SACN since the original NMA, please provide the data sheet which was approved in the NMA."*

Manatū Hauora has identified 3 documents within scope of this part of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed.

> *"Please provide a list of the following information for each Changed Medicine Notification (CMN) and Self-Assessable Change Notification (SACN) submittd since the New Medicne was approved on 16/4/1998:*
>
> *Application Date*
> *Change (description of change)*
> *Status (including date)"*

There have been no further changes via CMN or SACMN for this product. Therefore, this part of your request is refused under section 18(g)(i) of the Act, as the information is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	N/A	Sandrena TT50-4224-1 labels	Released in full.
2	10 October 2000	Sandrena TT50-4224-1 data sheet	
3	28 June 1996	Sandrena TT50-4224-1 user package leaflet	

Document 1

28 x 0.5 g sachets

SANDRENA 0.1% gel

Each 0.5g sachet contains
Oestradiol 0.5mg

Batch no:
Exp. date:

Manufactured by Orion Pharmaceutica
Distributed by NV Organon, The Netherlands
N.Z. Agents: Pharmaco (NZ) Ltd., Box 4079, Auckland

Organon

Keep out of reach of children.
Store at room temperature (not exceeding + 25°C).

PRESCRIPTION MEDICINE

28 x 0.5 g sachets

SANDRENA 0.1% gel

Each 0.5g sachet contains
Oestradiol 0.5mg

Directions: Apply 0.5 to 1.5g of gel
to the skin once daily as directed

Organon

FOR TOPICAL USE ONLY.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

91 x 0.5 g sachets

SANDRENA 0.1% gel

Each 0.5g sachet contains
Oestradiol 0.5mg

Batch no:
Exp. date:

Manufactured by Orion Pharmaceutica
Distributed by NV Organon, The Netherlands
N.Z. Agents: Pharmaco (NZ) Ltd., Box 4079, Auckland

Organon

Keep out of reach of children.
Store at room temperature (not exceeding + 25°C).

PRESCRIPTION MEDICINE

91 x 0.5 g sachets

SANDRENA 0.1% gel

Each 0.5g sachet contains
Oestradiol 0.5mg

Directions: Apply 0.5 to 1.5g of gel to the skin once daily as directed

Organon

FOR TOPICAL USE ONLY.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Calendar package:

0.5g Organon
SANDRENA 0.1 % gel

0.5g Organon
SANDRENA 0.1% gel

0.5g Organon
SANDRENA 0.1% gel

0.5g Organon
SANDRENA 0.1% gel

0.5g Organon
SANDRENA 0.1% gel

0.5g Organon
SANDRENA 0.1% gel

0.5g Organon
SANDRENA 0.1% gel

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

28 x 1 g sachets

SANDRENA 0.1% gel

Each 1g sachet contains
Oestradiol 1mg

Batch no:
Exp. date:

Manufactured by Orion Pharmaceutica
Distributed by NV Organon, The Netherlands
N.Z. Agents: Pharmaco (NZ) Ltd., Box 4079, Auckland

Organon

Keep out of reach of children.
Store at room temperature (not exceeding + 25°C).

PRESCRIPTION MEDICINE

28 x 1 g sachets

SANDRENA 0.1% gel

Each 1g sachet contains
Oestradiol 1mg

Directions: Apply 0.5 to 1.5g of gel
to the skin once daily as directed

Organon

FOR TOPICAL USE ONLY.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

91 x 1 g sachets

SANDRENA 0.1% gel

Each 1g sachet contains
Oestradiol 1mg

Batch no:
Exp. date:

Manufactured by Orion Pharmaceutica
Distributed by NV Organon, The Netherlands
N.Z. Agents: Pharmaco (NZ) Ltd., Box 4079, Auckland

Organon

Keep out of reach of children.
Store at room temperature (not exceeding + 25°C).

PRESCRIPTION MEDICINE

91 x 1 g sachets

SANDRENA 0.1% gel

Each 1g sachet contains
Oestradiol 1mg

Directions: Apply 0.5 to 1.5g of gel
to the skin once daily as directed

Organon

FOR TOPICAL USE ONLY.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Calendar package:

1g Organon
SANDRENA 0.1 % gel

1g Organon
SANDRENA 0.1% gel

1g Organon
SANDRENA 0.1% gel

1g Organon
SANDRENA 0.1% gel

1g Organon
SANDRENA 0.1% gel

1g Organon
SANDRENA 0.1% gel

1g Organon
SANDRENA 0.1% gel

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Stickpack:

Perforation
↓

1 g Organon
SANDRENA 0.1 % gel
Oestradiol 1mg
Batch no.
Exp. date

Perforation
↓

0.5 g Organon
SANDRENA 0.1 % gel
Oestradiol 1mg
Batch no.
Exp. date

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 2

INFORMATION FOR
HEALTH PROFESSIONALS

Data Sheet

SANDRENA

oestradiol 1mg/g (0.1%) gel

Presentation

Gel -a smooth and opalescent gel, where the active ingredient, oestradiol, is in dissolved form. The gel is packaged into single-dose sachets. One dose contains alternatively 0.5mg or 1.0mg of the active ingredient oestradiol.

Uses

Actions

The pharmacodynamics of SANDRENA are similar to those of oral oestrogens, but the major difference to oral administration lies in the pharmacokinetic profile.

The clinical efficacy of SANDRENA in the treatment of menopausal symptoms is comparable to that of peroral oestrogen. Combined with medroxyprogesterone acetate, percutaneous oestradiol treatment lowers total cholesterol without reducing the HDL cholesterol level.

Pharmacokinetics

SANDRENA is an alcohol-based oestradiol gel. When applied to the skin the alcohol evaporates rapidly and oestradiol is absorbed through the skin into circulation. To some extent, however, the oestradiol is stored in subcutaneous tissue from where it is released gradually into circulation. Percutaneous administration circumvents the hepatic first-pass metabolism. For these reasons the fluctuations in the plasma oestrogen concentrations with SANDRENA are less pronounced than with peroral oestrogen.

A 1.5mg percutaneous dose of SANDRENA results in a plasma concentration of about 340pmol/l, which corresponds to the level of early follicular stage in premenopausal women. During SANDRENA treatment the oestradiol/oestrone ratio remains at 0.7, while during peroral oestrogen treatment it usually drops to less than 0.2. The mean oestradiol exposure at steady state of SANDRENA is 82% compared with an equivalent oral dose of oestradiol valerate.

Otherwise the metabolism and excretion of transdermal oestradiol follow the fate of natural oestrogens.

Indications

Treatment of the climacteric syndrome associated with natural or artificial menopause (oestrogen deficiency symptoms, e.g. hot flushes, night sweats and urogenital atrophy).

Prevention of postmenopausal osteoporosis.

Dosage And Administration

SANDRENA can be used for continuous or cyclical treatment. The dose can be adjusted individually from 0.5g to 1.5g per day, corresponding to 0.5 to 1.5mg oestradiol per day. The usual starting dose is 1.0mg oestradiol (1.0g gel) daily and can be readjusted after 2 to 3 cycles.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

In patients with an intact uterus, it is recommended to combine the SANDRENA with an adequate dose of progestin for adequate duration, e.g. 12-14 consecutive days per cycle.

The SANDRENA dose is applied once daily, on the skin of the lower trunk or the right or left thighs, on alternate days. The application surface should be 1-2 times the size of the hand. SANDRENA should not be applied on the breasts, on the face or irritated skin. After application the gel should be allowed to dry for a few minutes and the application site should not be washed within one hour. Accidental contact of the gel with the eyes should be avoided. Hands should be washed after application.

If the patient forgets to apply a dose, it should be applied as soon as possible, unless the dose is more than 12 hours late. If the dose is more than 12 hours late, it should be skipped. Missed doses may induce breakthrough bleeding.

Contraindications

- Known, suspected or past history of breast cancer
- Known or suspected oestrogen-dependent tumours (e.g. endometrial cancer)
- Undiagnosed vaginal bleeding
- Confirmed venous thromboembolism [deep venous thrombosis (DVT), pulmonary embolism]
- A history of recurrent venous thromboembolism (VTE) or known thrombophilic disease in a patient who is not already on anticoagulant treatment (see **Warnings and Precautions**)
- Hereditary or acquired predisposition to venous thrombosis
- Acute or chronic liver disease or a history of liver disease as long as liver function tests have failed to return to normal
- Known hypersensitivity to the active substances or to any of the excipients.

Warnings And Precautions

- Before initiating or reinstituting hormone replace therapy (HRT), a complete personal and family medical history should be taken, together with a thorough general and gynaecological examination guided by the contraindications and warnings for use. During treatment periodic check-ups are recommended of frequency and nature adapted to the individual woman, and follow-up examination of the breasts and/or mammography should be carried out in accordance with current accepted practices, modified according to the clinical needs of the individual.
- Prolonged use without addition of a progestin may cause endometrial hyperplasia. Therefore, in women with an intact uterus, SANDRENA treatment should be combined with cyclic progestin administration. Withdrawal bleeding resembling normal menstruation will usually occur after each course of progestin. The cause of unexpected or prolonged uterine bleeding during therapy should be clarified. Atypical adenomatous hyperplasia of endometrium must be treated before entering oestrogen therapy.
- A careful appraisal of the risk/benefit ratio should be undertaken over time in women treated with oestrogen.
- If any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment, the benefits of treatment should be weighed against the possible risks. In these cases the patient should be closely supervised. It should be taken into account that these conditions may, in rare cases, recur or be aggravated during treatment with SANDRENA:
    - A history of oestrogen-dependent tumours
    - Leiomyoma, endometriosis, hyperplasia of the endometrium
    - Fibrocystic disease of the breast
    - A history of thromboembolic disorders or the presence of risk factors (see below)
    - Hypertension
    - Diabetes mellitus with vascular involvement
    - Liver disorders (e.g. porphyria, liver adenoma, icterus)

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

- Cholelithiasis
- Cholestasis
- Otosclerosis
- Migraine or (severe) headache
- Multiple sclerosis
- Galactorroea, elevated prolactin levels
- A history of herpes gestationis

- Oestrogens may cause fluid retention and, therefore, patients with cardiac or renal dysfunction should be carefully observed. In case of aggravation of asthma, epilepsy or diabetes mellitus HRT should be reconsidered.

- Changes in glucose tolerance have been observed in some patients on oestrogen therapy. SANDRENA may improve insulin sensitivity and elimination. For good glycemic control, diabetic patients should be monitored during the first months of therapy.

- Epidemiological studies have suggested that HRT is associated with a higher relative risk of developing VTE, i.e. DVT or pulmonary embolism. The studies find a 2-3 fold higher risk for users compared with non-users, which for healthy women amounts to one to two additional cases of VTE in 10,000 patient- years of treatment with HRT. The occurrence of such an event is more likely in the first year of HRT than later. Generally recognised risk factors for VTE include a personal history or family history, severe obesity (Body Mass Index >30kg/m^2) and systemic lupus erythematosus (SLE). There is no consensus about the possible role of varicose veins in VTE. The risk of VTE may be temporarily increased with prolonged immobilisation, major trauma or major surgery. As in all post-operative patients, scrupulous attention should be given to prophylactic measures to prevent VTE following surgery. Where prolonged immobilisation is liable to follow elective surgery, particularly abdominal or orthopaedic surgery to the lower limbs, consideration should be given to temporarily stopping HRT four to six weeks earlier, if possible. If VTE develops after initiating therapy SANDRENA should be discontinued. Patients should be told to contact their doctors immediately when they are aware of a potential thromboembolic symptom (e.g. painful swelling of a leg, sudden pain in the chest, dyspepsia).

- A re-analysis of original data from 51 epidemiological studies reported a small or moderate increase in the probability of having breast cancer diagnosed in women currently or recently using HRT. The findings may be due to an earlier diagnosis, the biological effects of HRT, or a combination of both. The probability of diagnosing breast cancer increased with duration of treatment and returned to normal in the course of five years after stopping HRT: breast cancers diagnosed in current or recent users of HRT are less likely to have spread outside the breast than those found in non-users. Between the ages of 50 and 70, about 45 women in every 1000 not using HRT will have breast cancer diagnosed, the rate increasing with age. It is estimated that among those who use HRT for 5 to 15 years, depending on the age of starting and duration of treatment, the number of additional cases of breast cancer diagnosed will be of the order of 2 to 12 cases per 1000 women.

- It has been reported that there is an increase in the risk of surgically confirmed gall bladder disease in postmenopausal women receiving oestrogens.

- An increased risk of developing systemic lupus erythematosus during HRT treatment has been reported.

- The use of oestrogen may influence the results of certain endocrine and liver function tests.

- Oestrogen therapy may be associated with elevation of plasma triglycerides leading to pancreatitis and other complications in patients with hereditary defects of lipoprotein metabolism.

Pregnancy And Lactation

SANDRENA is not indicated in women of child-bearing capacity. It has no contraceptive efficacy.

SANDRENA should not be used during pregnancy and lactation.

Effect On Ability To Drive And Use Machines

Oestrogens such as SANDRENA do not affect the ability to drive or use machines.

Adverse Effects

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Adverse medicine reactions reported during clinical studies with SANDRENA are usually mild and only seldom lead to discontinuation of the treatment. If they do occur, it will usually be during the first months of the treatment.

Very Common (>1/10)

- Reproductive: Breast tenderness

Common (>1/100, <1/10)

- Central nervous system: Headache
- Metabolic and nutritional: Oedema, weight increase
- Reproductive: Unscheduled vaginal bleeding or spotting
- Gastrointestinal: Nausea, vomiting, stomach cramps
- Application site: Skin irritation

Uncommon (>1/1,000, <1/100)

NA

Rare (>1/10,000, <1/1,000)

Central nervous system: Migraine

- Psychic: Changes in libido and mood
- Cardiovascular: Venous thromboembolism

Very Rare (<10,000), including isolated reports

- Cardiovascular: Hypertension
- Hepato-biliary: Alterations in liver function and biliary flow
- Skin and subcutaneous tissue: Rash

.nteractions

No interactions between SANDRENA and other medicines have been reported.

There are some indications that oestrogens may reduce the effects of antihypertensive, anticoagulant and antidiabetic agents. Concomitant treatment with potent inducers of liver enzymes (e.g. barbiturates, carbamazepine, griseofulvin and rifampicin) may reduce the plasma levels of oestradiol. The significance of these interactions in transdermal application has not been elucidated.

Overdosage

Generally, oestrogens are well tolerated even in massive doses. Possible symptoms of overdose include those listed under **Adverse Effects**. Treatment is symptomatic.

Pharmaceutical Precautions

Incompatibilities

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

No incompatibilities have been found.

Shelf-Life

3 years

Special Precautions For Storage

At room temperature (under +25°C).

Medicine Classification

Prescription Medicine.

Package Quantities

Stick-pack-single-dose laminate package in sizes of:

4 x 7 x 0.5g and 13 x 7 x 0.5g

4 x 7 x 1.0g and 13 x 7 x 1.0g

Further Information

Active ingredients and excipients

Oestradiol hemihydrate corresponding to 0.5mg oestradiol/dose (in single dose units containing 0.5g gel).
Oestradiol hemihydrate corresponding to 1.0mg oestradiol/dose (in single dose units containing 1.0g gel).

Carbomer 934, Sol. Natr. Hydroxid, Propylenglycol, Ethanol 96%, Aq. Purif.

Preclinical safety data

Oestradiol is a natural female hormone with an established clinical use, therefore no toxicological studies have been performed with SANDRENA. The necessary studies on the irritant effects of the gel have been studied in rabbits and skin sensitisation in guinea pig. Based on the results from these studies it can be concluded that SANDRENA very infrequently could cause mild skin irritation. The frequency of the occurrence of dermal irritation can be reduced by daily change of the application site.

Name And Address

Exclusive New Zealand agents:
Pharmaco (N.Z.) Ltd
P O Box 4079
Auckland
Telephone: (09) 377-3336

Date Of Preparation

10 October 2000

(CCDS 09.05.2000)

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 3

A-Ch. Bäckström 28.06.1996

TABLE OF CONTENTS

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 3

A-Ch. Bäckström 28.06.1996

Sandrena
gel for percutaneous administration

INFORMATION FOR THE PATIENT

Please read this page carefully, before you start to use this medicine. On the back of this leaflet you will find more information on Sandrena as well as some general advice on using medicines. If you have any questions or you would like further information, please ask your doctor or pharmacist.

1. WHAT YOU SHOULD KNOW ABOUT SANDRENA

1.1 Your medicine

The name of your medicine is Sandrena. It is a smooth alcohol-based gel, in which the active ingredient estradiol is dissolved. Estradiol is a natural hormone. Sandrena should be applied to the skin from where estradiol will be absorbed by the body.

The gel further contains: carbomer 934, sodium hydroxide, propylene glycol, alcohol and purified water.

The gel is packed in single-dose sachets, which contain 0.5 or 1.0 g gel. The gel in the sachets contains 0.5 or 1.0 mg of estradiol, respectively. Sandrena is supplied in packages containing 28 or 91 sachets of either dose.

Distributor:

N.V. Organon

Holder of marketing authorisation:

Orion Corporation, P.O. Box 65, FIN-02101 ESPOO, Finland

1.2 How Sandrena works and what it is used for

Sandrena contains estradiol. Estradiol is one of the female hormones your body makes. During and after the menopause (change of life), or after surgical removal of the ovaries, the estrogen production by the body decreases. This decrease may lead to hot flushes, sweatings and bone loss. Sandrena can be prescribed for the treatment of such complaints. Sandrena is not intended for contraceptive use.

On the back of this leaflet you will find more information about how Sandrena works and what it is used for.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 3

A-Ch. Bäckström 28.06.1996

1.3 Before using Sandrena

Sandrena may not be suitable for you if you suffer from certain medical conditions. Before you start using Sandrena make sure you tell your doctor if the answer is *yes* to any of the following questions:

- are you pregnant, or do you think you may be pregnant?
- are you breast feeding?
- have you recently had unexpected vaginal bleeding?
- do you have or have you recently had blood clotting disorders, such as thrombosis?
- do you have liver disease?
- do you have, or have you ever had, a tumour (e.g. a breast tumour or a tumour in your womb)?
- are you hypersensitive to any of the ingredients of Sandrena?

Caution: Before using Sandrena, it is also important to tell your doctor if you have or have ever had:

- disease of the heart or blood vessels,
- high blood pressure,
- high fat levels in your blood
- abnormal growth of tissue such as endometriosis (tissue resembling the inner lining of the womb in abnormal places) and fibroid growth of the womb,
- yellowing of the eyes or skin (jaundice)
- gall stones,
- affected hearing (otosclerosis),
- kidney disease,
- migraine or severe headache,
- benign breast disease,
- breast cancer in your family,
- diabetes,
- epilepsy,
- asthma,
- multiple sclerosis.

Regular medical check-ups are recommended during long-term treatment with Sandrena.

Other medicines may influence the effects of Sandrena, or Sandrena may interfere with the effects of other medicines. You must tell your doctor or pharmacist if you are taking (or intend to take) other medicines such as:

- medicines for high blood pressure,
- anticoagulants (medicines for prevention of blood clots),
- medicines for epilepsy or sleeplessness,
- medicines for fungal or bacterial infections,
- medicines for diabetes.

If you are pregnant or breast-feeding, or think you may be pregnant: *do not use* Sandrena.

Ability to drive or operated machinery. As far as is known, this medicine has no effect on alertness and concentration.

1.4 Using Sandrena properly

Use Sandrena as directed by your doctor.
You should also read the instructions on the label of your medicine.
If you are not sure how to use Sandrena ask your doctor or pharmacist.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 3

A-Ch. Bäckström 28.06.1996

How and when to use Sandrena. Use the amount of Sandrena that was prescribed by your doctor (that is, 0.5 g to 1.5 g). Apply the gel once daily to the skin of the lower trunk or the thighs. Spread the gel over an area about 1–2 times the size of the palm of your hand. Alternate between the right and left sides of your body. Sandrena should not be applied on the breasts, on the face, on irritated skin or to the vaginal area.

Allow the gel to dry for a few minutes after application. Accidental contact of the gel with the eyes should be avoided (the gel may be irritant to the eyes). Wash your hands after the application of the gel.

Sandrena is used in individually adjusted doses, either continuously or with cyclical intervals. Most patients can start with 1.0 g of Sandrena per day. If you have not had your womb removed in the past your doctor will also prescribe a progestagen to you. After each course of progestagen, a withdrawal bleeding resembling menstruation will usually occur.

The package contains a small refill box of plastic, for your medication for one week. With the help of this box it is easy to check if you have remembered to use your daily dose. Fill the box with 7 individual sachets. Mark on the side of the package the day and the date when you started the package. This day is day 1 on the plastic refill box.

Mark also every time you refill the box that you have done so, by ticking off the weeks marked on the side of the package. By doing so it will help you to remember when to take the progestagen your doctor might have prescribed for you. You should take the progestagen tablets by mouth according to your doctor's prescription.

What to do if you miss a dose. Apply the missed dose as soon as you remember, unless the dose is more than 12 hours late. If the dose is more than 12 hours late, just skip the missed dose. Missed doses may induce breakthrough bleedings.

What to do if someone has swallowed gel accidentally. If someone has swallowed some gel, there is no need for great concern. However, you should consult a doctor. Symptoms that may arise are nausea and vomiting: in females vaginal bleeding may occur after a few days. If needed, treatment is symptomatic.

1.5 Side-effects Sandrena may have

Sandrena may cause side-effects in some people.
These could be: breast tenderness, headache or migraine, fluid retention in tissues, usually marked by swelling of ankles or feet, increase in body weight, unexpected vaginal bleeding or spotting, changes in libido and mood, nausea or stomach cramps, hypertension and skin irritation.

Contact your doctor if any side-effect becomes troublesome or continues. It is also important to tell your doctor or pharmacist, if you experience any other unusual or unexpected symptoms during treatment with Sandrena.

1.6 Storing your medicine

Keep your Sandrena in a safe place out of reach of children. Check if there are special storage conditions written on the box. The expiry date (sometimes written as 'exp') is also printed on the container – do not use Sandrena after this date.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Document 3

A-Ch. Bäckström 28.06.1996

2. MORE ABOUT SANDRENA

The active substance of Sandrena is estradiol, one of the natural estrogens (female sex hormones). Estrogens (also called oestrogens) are mainly produced by the ovaries. They are necessary for the normal sexual development of women and for the regulation of the menstrual cycle during childbearing years. When women get older the ovaries gradually produce less estrogen. The period in which this happens is called the climacteric. If the ovaries are removed surgically (ovariectomy) before the climacteric period, the decrease in estrogen production occurs very abruptly.

In many cases the decrease in estrogen production leads to the well-known climacteric complaints, such as hot flushes and sweatings, and bone loss. The shortage of estrogens may cause the vaginal wall to become thin and dry. As a result, sexual intercourse may become painful and infections occur. Estrogen deficiency can also cause problems such as urinary incontinence and recurrent cystitis. These complaints can often be relieved by using medicines containing estrogen. It may take several days or even weeks before you notice an improvement.

Another favourable effect of estrogens is that they can stop accelerated bone loss which occurs in many women during the climacteric. There are strong indications that estrogens also have a favourable effect on heart and blood vessels.

Sandrena is applied to the skin. Estradiol is absorbed through the skin into the blood.

Unless your womb has been removed, the treatment should be combined with an additional hormone, a progestagen. This hormone opposes the stimulating effect of estrogens on the lining of the womb. After completion of a course of progestagen, the inner lining of the womb will usually be shed as an episode of vaginal bleeding (resembling a normal menstrual bleed).

3. GENERAL THINGS TO REMEMBER

1. This medicine has been prescribed only for your current medical problem. Do not use it for other medical problems.
2. Do not allow other people to use your medicines and do not use medicines meant for other people.
3. Tell any doctor treating you what medicines you are taking. Always carry a medical information card stating which medicines you are using. This can be very important in case you are involved in an accident.
4. Return unused medicines to the pharmacy for disposal.
5. Make sure other people you live with or who look after you read this information.

This information was last updated in June 1996.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982