CONSUMER INFORMATION
Product Monograph Part III

PrVANTAS®
histrelin
histrelin acetate subdermal implant, 50 mg

Paladin Labs Inc.

Submission Control No. 092567

The Consumer Information Section (Part III) of the Product Monograph for VANTAS® has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on March 10, 2006 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PRODUCT MONOGRAPH

Pr VANTAS®

(histrelin acetate subdermal implant) (Professed)

Subdermal Implant 50 mg

Luteinizing Hormone-Releasing Hormone (LHRH) Analogue

Paladin Labs Inc.
Montreal, Quebec

Date of Preparation:
March 10, 2006

Submission Control No: 092567

PART III: CONSUMER INFORMATION

VANTAS®

(histrelin acetate subdermal implant) 50 mg
(delivers approximately 50 µg histrelin/ day)

This leaflet is part III of a three-part "Product Monograph" published when Vantas® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Vantas®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- Your doctor has prescribed Vantas® as part of your treatment for prostate cancer.

What it does:

Vantas® is a drug delivery system that contains the medicine histrelin acetate and is placed under the skin. It looks like a small, thin flexible tube. Your doctor places Vantas® under the skin of your upper, inner arm so that it can deliver the medication to your body continuously for 12 months.

Vantas® is a Luteinizing Hormone-Releasing Hormone (LHRH) Analogue also known as a GnRH agonist. It works by reducing testosterone produced by the testicles. This lowers the amount of testosterone in the body. Testosterone appears to be needed by prostate cancer cells. Usually prostate cancer shrinks or stops growing when the body's supply of testosterone is lowered. By lowering the amount of testosterone in the body, Vantas® may help relieve the pain, urinary problems, and other symptoms of prostate cancer. You may notice an improvement in your symptoms approximately 1 month after receiving Vantas®. Vantas® is not a cure for prostate cancer. Once Vantas® is removed by your doctor, your body will start producing testosterone again.

When it should not be used:

Do not use Vantas® if you are allergic or hypersensitive to the histrelin acetate, to any ingredients in the formulation or component of the implant or to drugs called LHRH agonists or GnRH agonists (see: What the non medicinal ingredients are).

Do not use Vantas® for women who are or may become pregnant, for nursing mothers and for women in general.

In pregnant women, Vantas® may cause harm to the baby or a miscarriage (losing the baby).

Vantas® was not studied in children and should not be used in children under 18 years of age.

What the medicinal ingredient is:

Histrelin acetate 50 mg (delivered as approximately 50 µg histrelin/day)

What the nonmedicinal ingredients are:

Sodium Chloride Solution
Stearic Acid
Delivered within a hydrophilic polymer implant.

What dosage forms it comes in:

Vantas® is a subdermal imp lant. It looks like a small, thin flexible tube.

WARNINGS AND PRECAUTIONS

BEFORE you use Vantas®, talk to your doctor or pharmacist if:

- You have any allergies to this drug, or its ingredients, or to components of the implant
- You have a strong family history of osteoporosis
- If you have or have had liver disease
- If you take or have taken drugs such as anticonvulsants or corticosteroids

INTERACTIONS WITH THIS MEDICATION

Before your treatment with Vantas®, tell your doctor about all the medicines you take, including prescription and non-prescription drugs, vitamins and herbal remedies. During your treatment with Vantas® do not start taking a new medicine before checking with your doctor or pharmacist.

It is not known if Vantas® and other medicines can affect each other.

PROPER USE OF THIS MEDICATION

The recommended dose of Vantas® is one implant for 12 months. One implant provides continuous release of drug for 12 months.

There may be some pain and discomfort during and after insertion and removal of Vantas®. Please refer to "Side Effects and What to Do About Them".

Vantas® is placed under the skin of your upper, inner arm. Your doctor will numb your arm, make a small incision (cut), and

then place Vantas® under the skin. The cut will be closed with special surgical tape and covered with a bandage. Keep your arm clean and dry and do not swim or bathe for 24 hours. The pressure bandage can be removed at that time. You should not remove the surgical strips they will fall off on their own in several days. Avoid heavy lifting and exercise for 7 days. Avoid bumping the site for a few days. After the cut has healed, you can go back to your normal activities. Your doctor will give you complete instructions.

Remember to see your doctor for routine checks on your condition and to ensure that Vantas® is present and functioning in your body. Your doctor will do blood tests to check on your response to treatment with Vantas®. For example, your doctor may check your prostate specific antigen (PSA) or testosterone levels.

Vantas® may be difficult to feel under your skin. If it cannot be located under your skin at the time of removal, your doctor may order special tests, such as ultrasound or CT scan in order to locate it.

Vantas® must be removed after 12 months of therapy. Your doctor may insert a new Vantas® to continue therapy.

Given the design and delivery method of the drug, it is unlikely that an overdose may occur.

Missed Dose:

Contact your physician or pharmacist as soon as you realise that you have missed your scheduled appointment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Vantas® may cause an increase in the blood levels of testosterone during the first week after it is inserted. As a result your symptoms may get worse for a few weeks. You may also get new symptoms.

You may also experience palpitations (pounding heart beat), abdominal discomfort, nausea, muscle pain, bone pain, joint pain, and/or urination problems (difficulty passing urine or having to go the bathroom too often).

Bruising and redness may occur. These reactions, if they occur at all, are usually mild and heal without treatment within 2 weeks. If they do not heal or if you have unusual bleeding, contact your doctor.

Vantas® can be expelled from your body through the original incision site. This occurs infrequently. You may notice the system being expelled, or rarely, the system may be expelled without you noticing it. If you believe Vantas® has been expelled from your body contact your doctor.

Vantas® can cause a loss in bone mineral density. This can lead to thinning of the bones (osteoporosis).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

		Talk with your doctor or pharmacist		Call your doctor right away
Symptom / effect		**Only if severe**	**In all cases**	
Very Common	Hot flashes	✓		
Common	Tiredness	✓		
	Increase in Weight	✓		
	Implant site reaction	✓		
	Erectile dysfunction (impotence)	✓		
	Enlargement of breasts	✓		
	Testicles become smaller		✓	
	Trouble Sleeping	✓		
	Lowered libido	✓		
	Constipation	✓		
	Headache	✓		
	Trouble Urinating		✓	
Uncommon	Bone pain			✓
	Weakness or loss of feeling in legs			✓
	Blood in Urine			✓
	Cannot Urinate			✓

These side effects can happen throughout the entire time of your treatment, not only at the beginning.

This is not a complete list of side effects. For any unexpected effects while taking Vantas®, contact your doctor or pharmacist.

HOW TO STORE IT

Store under refrigeration (2 to 8 °C). Protect from freezing.

Protect from light.

Keep in a safe place out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Health Canada by:

toll-free telephone: 866-234-2345
toll-free fax: 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be found at:
http://www.website.document or by contacting the sponsor, Paladin Labs Inc., at:
1-888-550-6060

This leaflet was prepared by Paladin Labs Inc.

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