

July 1, 1993

Amersham Holdings, Inc.

2636 S. Clearbrook Drive
Arlington Heights, IL 60005
tel (708) 593-6300

A. Bert Davis, Regional Administrator
Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137


The Health Science Group

Dear Mr. Davis:

The Illinois Department of Nuclear Safety has issued an amendment to our Medi-Physics License IL-01109-01 permitting the distribution of Metastron (Strontium-89 Chloride) to specific licensees.

Considerable interest has already been expressed in the product which has been cleared for marketing by FDA for palliation of pain in patients with metastatic bone cancer. I am sending you this information since I believe you will be receiving inquiries from some of your licensees.

I am enclosing a copy of the package insert and patient information sheet that accompanies each vial of the product.

Please call me (708-593-6300, extension 379) or the Division of Radioactive Materials, Illinois Department of Nuclear Safety (217-785-9947) should you have any questions concerning the nuclear licensing of this product. We will be pleased to assist you.

Sincerely,



Bryan W. Baker, Ph.D.
Corporate Manager
Nuclear Licensing and Industrial Liaison

BWB/jc

Enclosures

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METASTRON[®]

(STRONTIUM-89 CHLORIDE INJECTION)

Information for Patients

What is Metastron?

For many years doctors have used certain types of radiation to relieve the pain experienced by people like yourself. Metastron is a new development in this type of treatment. Metastron (Strontium-89 Chloride Injection) contains small amounts of a specially selected form of radioactive strontium, chosen because almost all of its radiation is given to the area where it is absorbed. This allows it to deliver therapy precisely where it is needed.

Why has Metastron been prescribed for me?

For many people, Metastron is more appropriate than other types of therapy. It has been prescribed for you as it seems likely that it will be the most suitable treatment in your case.

What effect will Metastron have?

At first you will feel no effect at all. You may even feel a slight increase in pain for two or three days beginning two or three days after injection. This is quite normal, and your doctor may suggest that you temporarily increase your dose of pain killers until the pain is under control.

After about one to two weeks, sometimes a little longer, you should begin to feel the pain diminish. This reduction in pain should continue and the effect should then last for several months.

Are there any side effects?

None that you will normally notice. You can eat and drink normally and there is no need to avoid alcohol or caffeine unless you have already been advised to do so. There may be a slight fall in the number of cells in your blood and your doctor will want to carry out periodic, routine blood tests. If you have any concerns you should of course talk with your doctor.

Should I stop taking pain killing drugs?

Your doctor may advise you to continue taking your pain killing medicine until Metastron begins to become effective. You may then be advised to reduce the dose of your pain medications gradually. Your doctor may want to continue reducing the dose and eventually you may not need pain killers at all. If you have any doubts, consult your doctor.

What about other treatments?

Your doctor will advise you about other treatments that are required. You may have been receiving hormone injections or tablets and your doctor may wish you to continue with these.

What activities can I undertake?

The injection will not prevent you from doing anything that you were already doing. As Metastron begins to relieve the pain, you may find that you can tackle activities that were previously too difficult or too painful. Usually there is no problem with this, but be careful not to overdo it! If you are in any doubt, seek your doctor's advice.

Who should I tell that I have received Metastron?

You should tell any health practitioner who is giving you medical treatment that you have received Metastron, and show them this leaflet.

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METASTRON[®]

(STRONTIUM-89 CHLORIDE INJECTION)

Information for Patients (continued)

What precautions should I take?

The effects of Metastron are confined within your own body. Other people will not be harmed through bodily contact with you.

During the first week after injection, Metastron will be present in your blood and urine. It is therefore important that you should follow the common sense precautions listed below for one week.

- Where a normal toilet is available it should be used in preference to a urinal. The toilet should be flushed twice.
- Wipe up any spilled urine with a tissue and flush it away.
- Ensure that you always wash your hands after using the toilet.
- Immediately wash any linen or clothes which become stained with urine or blood. Wash them separately from other clothes, and rinse thoroughly.
- If you use any urine collection device, take advice on its use from your doctor.
- If you should cut yourself, wash away any spilled blood.

What happens if my pain returns?

In many people who receive Metastron, the effect lasts for several months. If pain returns, you should consult your doctor. The doctor may give you another Metastron injection if this is the most appropriate treatment.

Further Information

Metastron may only be prescribed and administered by a qualified physician. Your doctor has further information about your treatment and you should not hesitate to ask if you have any questions or concerns.

Medi-Physics, Inc.
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