generichealth
Lupin Group Company

DOCTOR'S COPY

PATIENT CONSENT FORM

TERIPARATIDE LUPIN

teriparatide 250 micrograms/mL injection

Your doctor has evaluated your current medical condition and recommends that you start therapy with Teriparatide Lupin. Before you begin treatment with Teriparatide Lupin, you are required to sign this form.

By signing this page, you are confirming the following:

- Your doctor has described the benefits and risks of Teriparatide Lupin. Teriparatide Lupin works by activating cells in the bone to form new bone, increasing both bone mineral density and bone strength. Using this medicine each day will protect your bones by making them stronger and your future risk of fracture will be reduced.
- Your doctor has explained that you should **not** receive Teriparatide Lupin treatment if you have any of the following:
  - you have Paget's disease of the bone;
  - you have a history of unexplained elevation of alkaline phosphatase in blood; or
  - you have had prior radiotherapy (radiation therapy) involving the skeleton.
- As with most drugs, there are risks associated with taking Teriparatide Lupin (teriparatide). Your doctor has discussed these risks with you and answered your questions. The risks associated with Teriparatide Lupin pertain to the following:

  In rats that were treated with teriparatide for more than a quarter of their lifetime, teriparatide caused some rats to develop osteosarcoma, a bone cancer. The potential to cause osteosarcoma in rats was increased with higher doses and longer periods of treatment.

  Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about 4 out of every million people each year. **There is one report of osteosarcoma in a patient administered teriparatide for 14 months. Due to the complex medical history, cause and effect between teriparatide and osteosarcoma could not be established. At present, it is not known whether humans treated with teriparatide would have an increased chance of getting osteosarcoma.**
- **The use of Teriparatide Lupin is restricted to 24 months lifetime duration.**
- You have read the Consumer Medicine Information (CMI) leaflet and this Patient Consent Form.
- You will receive a copy of this Patient Consent Form to keep for yourself and show on request to your pharmacist. You will need to keep this form to show to future treating doctors.

Name of Patient/Guardian: _____

Signature of Patient/Guardian: _____ **Date:** _____

Treating Doctor's Statement

I have fully explained the nature and purpose of the treatment with Teriparatide Lupin (teriparatide) and the potential benefits and risks associated with that treatment to the abovementioned patient. I have asked the patient if they have any questions regarding this treatment or the associated benefits and risks and have answered those questions to the best of my ability.

Name of Treating Doctor: _____

Signature of Treating Doctor: _____ **Date:** _____

Note to Treating Doctor:
You should retain a signed copy of this informed consent with the patient's medical records.

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Name of Treating Doctor: _____

Signature of Treating Doctor: _____ **Date:** _____