

MKUC " © T © P " D N I U

1. D G G T " V K D D " © T © P © P " C F K "

ACTONEL 35 mg Film Tablet

4 0 " M C N V C V H " X G " M C P V V C V H " D k N G O

Etkin madde: Her bir film tablet;

35 mg risedronat sodyum (32.5 mg risedronik asite e f g l g ± g t k t 0

[c t f , o e ,

madde:

Laktoz monohidrat 126 mg

[c t f maddeler k ± k l e d c m , p , | 0

3. FARMAS " V FORM

Film tablet

Bir v c t c BSN, p ff kc vg ct t c 35 mg p d f c u o y a h d k ± k c o ± n t u k m u c u , f i l m m c r n ,
tablet.

4. M N P " M G N N M N G T

6 0 3 0 V g e n d i k a s y o n l a r m

Postmenopozal osteoporoz ve erkek osteoporozunun tedavisinde endikedir.

4.2. Pozoloji ve uygulama g m n k

Pozoloji:

[g v k m 3 k p g n g f t o f l g " p j c h v c f c " d k t " m g | " c n , p c p " 5 7 " o i "
i Ñ p a f i g ' p o c n , f , t 0

W { i w n c o c v e ' u Ñ m g u k , <

Tablet her hafta c { p Ñ p d g , p o c n , f , t 0

É Risedronat sodyumun absorpsiyonu yiyeceklerden ve polivalan katyonlardan etkilenmektedir (Bkz. 4.5. F k g t " Ñ v Ñ d i l e k t i l e k o n e g f k ' g v m k n g k o "
ekilleri), bu nedenle yeterli emilimin u c n c p o k a s t a l a r " A C T O N E L 35 o i) , "

m c j x c ¾ p c ilf yemekt en, f k v g, t d t k A p n g t ife g e k l e r d e n g (s u c f , , p f c + " 30 dakika ¾ p su g l e b i r l i k t e c n o c A C T O N E L t 30 mg { c n p s u i l e e c c n , p o c n , f , D c | m a d e n u w n c t k a l s i y u m p k o n s a n t r a s y o n u { A m u g m f w w p w p c . t " , p m w n n c p , g e r e k m e k t e d i n u (B k z . 5.2. F a r m a k o k i n e t i k ¾ | g n) n k m n g t

E C E V Q P G N " 5 7 " o i " v c d h a s t a l a r , k k " n c m o c c { f , , f a r m a k o k i n e t i k l e r i c i p A p " k ± g t k b i n A C T O N E L 35 mg tablet c n o c n , D a h a s o m r a c h a s t a l a r n o r m a l r u t i n l e r i n e f ¾ p g t a b l e t l e r i ¾ p e g f d g g p n k t n g f k m ¾ g a l m y a d e v a m p g e t m e l i d i r l e r . m a k l e t c { p A p " n , p o c o c n , f , t 0

W { i w n c α c " g m n k

Tablet d A v o l u m u n d a ¾ p k { w v w n c e m i l m e m e f i y e t a ± k p g p o g o g n k f i k l e y e 0 " V c d n w n c o c u , p c n " o c m A C T O N E L 35 mg tablet dik pozisyonda ve bir bardak su (× 120 ml) i l e c n , p o H a s t a l a r f t a b l e t i 0 c n f , s o m r a 30 p f c m k m c " { c v o c o c r (B k z . b ¾ n A . 4 " | g n w n n w p f , c o t v e , ¾ p e n t g) o n g t k

Diyetle c n , k a l s i y u m v e D v i t a m i n i y e t e r l i f g k a l s i y u m v e D v i t a m i n t a k v i y e s i f A l a c i d i r .

Q u v g q r q t q | f c " d k h q u h q p c v " v g f c x k u k p k p " q r v k o c i i g t g m n k n k k " ¾ | g n n k m n g " 7 " x g { c " f c j c " h c | n c " m w n u q f { w o r o w p c p u k { g n " t k u m n g t k " x g " { c t c t n c t , p c " f f g g t n g p f k t k n o g n k f k t 0

" | g n " r q r A n c u { q p n c t c " k n k m k p " g m " d k n i k n g t <

D ¾ d t g m 1 M c t c e k g t " { g v o g | n k k <

Hafif ya da orta derecede d ¾ d t g m o g o l a m h a s t a l a r d a d o z c { c t n c g e r e k u , p c y o k t u r . T k u g f t q p c v " u q f { w o w p " k f f g v n k " d ¾ k l e r a n g i m " { g v o 30 ml/dak.'dan f A A n w n n k o p t r e n d i k e d i r (B k z . 4.3. K o n t r e n d i k a s y o n l a r v e 5.2.

Farmakokinetik ¾ | g n n M c n t n g e t k g 0 g o t g o l a n n h a s t a l a r d a d o z c { c t n c g e r e k u , p c " y o k t u r .

R g f k { c v t k m " r q r Ñ n c u { q p

T k u g f t q p c v " u q f { w o ø w p " g v m k n k n k k " x g " i Ñ x g p n k n
{ c , p " c n v , p f c m k " ± q e w m n c t f c " ¾ p g t k n o g |

I g t k { c v t k m " r q r Ñ n c u { q p <

I g p ± " j c u v c n c t d a d { " h a s t a l a r d a , * n @ c 8 2 v " d { k c h q f { " c t , f c p t n y e n p , , o o " . "
eliminasyon benzer q n f w w d o z f c c p { c t n c g e r e k i , y o k t u r . B u d u r u m ,
postmenopozal r q r Ñ n c 75 { { q c p f " c x . g " Ñ u v Ñ h a s t a l a r d a d a " i ± ¾ q u m v " g i t c k n n o , k

4.3. Kontrendikasyonlar

- Risedronat sodyum x g { c " h q t o Ñ { n c c t u f { n o p u l e r d e n k b i r i n e m c t , " c , t
f w { c t n , n , m
- J k r q m c n u g o k " * D m | 0 " 6 0 6 0 " ¾ | g n " m w n n c p , o " w { c t , n
- Gebelik ve laktasyon
- k f f g v n k " d ¾ d t g m " { g v o g | n k k " * m t g c v k p k p " m n g t g

4.4. " | g n w n n w p f , c o t ' v e h p n t g , o n g t k

Oral bifosfonat m w n c p , o , " k a n s e r i r i s k i n i n c e i t w u d k b i l d i r e g d k p | k ,
± c m a l a r b u l u n m a k l a b i r l i k t e b u i l i k i n e t o l a r a k m c p , v n c p B u n e d e n l e , v , t 0
D c t t g v " ¾ v e y a h i c e i u w u t v q ¾ | t c g h z a m a n d e n c t v o , " k a n s e r r i s k i i w u
olan hastalarda, bu k n c ± n c t , p " m w n n c p , , t o , p f c p " m c ± , p , n o c n ,

Bifosfonatlar ile tedavi g f k n g p " j c u v c n c t f c " c v k r k m " d ¾ h v g h g t
m , t , i n ¾ t c Ñ t n " g d k n k t 0 " D w " m , q t n , o n c m y a t d a | n i n i n p a l g t r a v m a k i l e n g " v t c
i g m e k t e d i r . B i f o s f o n a t k u l l a n a n v e u y l u k y a d a m c u c , m t i l e u b a v u r a n h a s t a l a r
c v k r k m " e s i i l e t f , g n " g t Ñ n r g j p f b k h a s t a l a r d a b i r e y s e f r i s k t y o r a r a n a l i z i n e i ¾ t g "
bifosfonat tedavisinin kesilmesi i Ñ p m e g g e l e b i l i r .

Yiyecekler, k ± g e (g u m f n , g t , v e p f o l i v a l a n k a t y o n l a r (k a l s i y u m , m a g n e z y u m , d e m i r
x g " c n Ñ g i l i) p k w g v g p Ñ d t k Ñ p d n k g h t q u h e p i l i m i n i n e t k i l e r , p b u n e d e n l e
ACTONEL 35 mg ile c { p a m a n d a c n , p o c (B k z . n 4 , 5 . f f k g , t d Ñ d t k Ñ p i l a g t
g v m k n v e f k k o g g g t m " k r e k i l l e r i k) o u v g g p v g n p k u l a n m a k g ± d o p ¾ p g t k n g t k p g
u , m w f e v e n g e r e k l i d i r (B k z . 4 . 2 . P o z o l o j i v e u y g u l a m a g) m n k

Osteoporoz tedavisinde d k h q u h qgpvcvkncf k, k p m i k mineral { q w p n w w p w p ve/veya ¾ p e gmf, g t p, n n o c ü l i , k i l i d i r . c

n g t k e ' y a { t e k b a ' x a p m , t k , ± m i l i m i k r i s k h c m v ¾ t x n c g t t h i r , p i k o s f o n a t i l e v g f c x k { g e d e m i f g n d c n c f " k p t 0

¥ q m " { c l e r d e , (> 8 0 m k c) k r i s e d r o n a t s o d y u m d a h i l d k h q u h q g p v c m v k n p c n t k , p k p k d e s t e k l e y e n m c p , u v , n p c , (B k z n 5 , 1 . f F a r m a k o d i n a m i k ¾ | g n n k m n g t + 0

Bifosfonatlar k n g " ¾ | g a s t r i t i c b ¾ k | v q . h c ã g u g t c u { g a s t r o d u o d e n a l x g " ã n u g t c a u t { c q u p , n p c f t o ÷ l l u d n u t u r . B p n e d e n l e , a c d a k i d u r u m l a r d a d i k k a t l i q n w p o c n , f , t <

É U v t k m v ã m ç i x g { ç c " i k g k k ¾ k g p f g c ' i d v q u g e c i k m e c ¾ { n p ã f u c ã o l a n h a s t a l a r d a

É Tablet in c n , p o c s o n r a ç n f i z 3 0 d a k i k a d i k p o z i s y o n d a d u r a m a y a n h a s t a l a r d a

É Risedronat aktif x g { c " { c m , ¾ p | " q | h o c y a c w ã u g a s t r o i n t e s t i n a l p r o b l e m l e r i o l a n h a s t a l a r a v e r i l i r s e (b i l i n e n D c t t g v " ¾ | q h c i w u " f c j k n +

n c e , " t g ± g v g c " n g k f o g c p v m n g c v , " p g c q " o f g k p n k p " ¾ x p v g t o i k v p r k c " o j c c n u , v " q n ¾ u | q h c i w u " t g c m u k { q p w " k o g u s u r d a h a s b e c n n e v t { , c " t x o g c { n c , " f d , g H a s t a l a r a , f k u h c l k . " { w v o c " v u g , t t p c a n , " p ç c t ' , c " x g { ç " t g g p k { c p o c u , " i k d k " ¾ | q h c i w u " v c j t k k " u g o r v q o n c t , v c n k o c e t i d i r . " x g t k n o

ACTONEL 35 mg tedavisine ba n a d a n o ¾ p e h i p o k a l s e m i t e d a v i e d i l m e l i d i r .

ACTONEL 35 o i " v g f c x k i k e n p k e m i k d e m i n e r a l p o g v c d q n k f | k o c g u t , p , d q | w m i p a r a t i r o i d d i s f o n k s i y o n u , h i p o v i t a m i n o z D g i b i) t e d a v i e d i l m e l i d i r .

R t k o g t " q n c t c m " k p v t c b i f o s f o n a t l a r d a h i l i k a n s e r p e d a v i s i a l a n n c p o , h a s t a l a r d a , g e n e l q n c t c m " i f v e / v e y a h o l g a m e h f e k s i y o n l a (o s t e o m i y e l i t d a h i l) b i r l i k t e ± g o s t e o n e k r o z u b i l d i r i l m i t i r . B u j c u v c n c t c p { " t k e m o t e r a p i v e w k o r t i k o s t e r o i d l e r a l a n j c u v c n ç t e o n e k r o z u , o r a l b i f o s f o n a t l a r a l a n o s t e o p o r o z l u h a s t a l a r d a d a d k n f k t k n o k v k t 0

G n k m " g h ç g n p v ¾ t t l n u g m i k " " * m c p q i v g g t . c ' r ' l m g ' o n q ç t g v t k e n r ç u v ' g

ACTONEL tabletler laktoz k \pm g t o g Nadr gmfc kn t, \emptyset , o u ckn p "v iq c n n g a p p c v p u " .
laktoz ye v o g | y a d a g l i k o z - g a l a k t o z m a l a b s o r p s i y o n p r o b l e m i o l a n j c u v b u r k a t e p
m w n n c p o g e r e k i c n c t ,

4.5. F k v g , t d Ā d t k Ā p l e t k i l e H e v e f k e t g i l e k o " g m k n n g t k

Risedronat sodyum ile resmi g v m k n g k o { ϵ r c , n n , o c B a m n l a v i r l i k t e k l i n i k
 \pm c n , o f c k n v g t t d " d k " Ā t Ā p n g t q n g c " t c c t m e " u $\frac{3}{4}$ p p g f r g " k m k n o k " p u k m r " v c p o
T k u g f t q p c v " u q f { w o w p I I I i q Ā u p v n g Ā q n r " q n t v q n | n " c \pm p c , s a l i s i l i k c , n " c H t c , | p
c u k v " m w n n c p , n o n s t e r o i d c p y k R p ' h ' n c $\frac{3}{4}$ p U v C m w n n " k p c ϵ 45 q t c p , " ,
q n c t c m " d k n f k t k n o k v k t 0 " " R q F a z I I g \pm p c q n r , q | o c c n u " , n p c f f c , " p o
s a l i s i l i k a s i t v e y a N S A I m w n n c p , o , ũ , j t c c u $\frac{3}{4}$ c (u n c $\frac{3}{4}$) , p p " f c " d k n f k t k n o k
Risedronat sodyum ile tedavi edilen hastalarda f Ā | g a s t r i s a l i s i l i k a s i t v e y a N S A I
m w n n c p (h a f t a d a 3 v e y a f a z l a " f a z l a i Ā p Ā u " v " " i c u v t q k p v g u v k p c n " c f
m q p v t q n " j c u v c n c t , p m k p g " d g p | g t f k t 0
Uygun i $\frac{3}{4}$ t Ā n f Ā s e d r o n a t s o d y u m $\frac{3}{4}$ u v t e d e s t e k t e d a v i s i i l e e " | c o c p n , " q n c t
m w n n c p , n c d k n k t 0

R q n k x c n c p " m c v v , (d Ā d t k Ā p k a l s i y u m , m a g n e z y u m , d e m i r v e c n Ā o k p { w o
g i b i) i l e g " | c m v e r p m c i s p r o n a t , s o d y u m u n e m i l i m i n i e t k i l e y e c e k t i r (B k z . 4 . 4 .

" | g n " m w n n c v e $\frac{3}{4}$ p n g q n g t k e 0 ,

Risedronat sodyum sistemik olarak metabolize olmaz, sitokrom P450 enzimlerini
k p f Ā m n g Ā g o Ā n d a p r o t e i n l e r e d c n c p , t 0

4.6. Gebelik ve laktasyon

Genel tavsiye

Gebelik kategorisi: C

¥ q e v m " w p o t a n s i y e l i b u l u n a n m c f , p n c t 1 F q (K o n t r a s p s i y o n) t q n Ā "

Hamile m c f , p A C T O N E L ' i n y e t e r l i v e i y i m q p v \pm c m n Ā o k t u r . u $\frac{3}{4}$ q e v m " w t o c "
p o t a n s i y e l i q n c p " m c f , p n c a n p t ' n c g e p m ' Q p c o n k o n c g n " c t , " G v c g x t u k { g "
A C T O N E L ' i n a n n e v e h g v p o t a n s i y e l { c t c t , " m i s k i n d e n f a z l a y s a A C T O N E L
h a m i l e l i k u , t c m w p i f c p , n o c n , f , t 0

Gebelik f ¾ p g o k

Hayvanlar \tilde{A} | g t k p f g n c v p, "c t n c t " \tilde{A} t n g u k g u k v g u k p k p " d w n w p f w
nsanlara { ¾ p g potansiyel risk bilinmemektedir. T k u g f t g e b e c m e f p p n c t f c
m w n n c i p i k i n y e t e r l i v e r i m e v c u t f g k n f k t 0
ACTONEL gerekli q n o c f g e b e l i k f ¾ p g o k w p f i g p , n o c o c n , f , t 0

Laktasyon f ¾ p g o k

T k u g f t k p p u c v p, "p a \tilde{A} y \tilde{A} { n g b i l i n m e m e k t e d i r J c { x c p n c t " \tilde{A} | g t k p f g
 \pm c m a l a r, r i s e n f t q p c u \tilde{A} , v p n g " c v , n f , , p , " i ¾ d u r d u r u l u p g m v g f k
f w t f w t w n o y a d a A C T O N E L t e d a v i s i n i n d u r d u r u l u p f w t f w t w n o c { c e c , p c l
m c \pm p p c n , p , n o c k i n c n e c t c, t p " c x' g k t n k n k t m g p . " g o | k t o g p k p "
ACTONEL tedavisinin emziren anne a \pm , d a n, h p c { d i k k a t e , c n , p o c n , f , t 0

© t g o f g v g p g k 1 H g t v k n k v g

Hayvanlar \tilde{A} | g t k p f g n c n p a l ' a r c \tilde{A} t e g o v g, " t v q m d u w k n u w k p v f g v t k w p t g v p o k

6 0 9 0 " e c n a k i n e n' w n n c p , o , " \tilde{A} | g t k p f g m k " g v m k n g t

C t c \pm " x g " o c m k p g " m w n g n v a m p k o u c k "" { i g ¼ v t g \tilde{A} p n g o g k o " k \tilde{A} | v g k t t k 0 p g "

4.8. stenmeyen etkiler

Risedronat sodyum Faz III klinik \pm c n , o c n c t f c " β σ u ϱ ϱ ϱ ϱ " \tilde{A} \pm g n t k p f m
M n k p k m " \pm c i n ¾ | m o g e m g e p t " f a t k i l e m i n g p q g v g g p j ' o r t a k i d d e t t e g o l l u p ,
genellikle tedavinin kesilmesini i g t g m v k . t o g o k v k

Osteoporozu olan ve 36 ay risedronat sodyum 5 o i 1 i (n=5020) veya plasebo
(n=5048) ile tedavi edilen postmenopozal m c f , p n c r t F a z III p m n k p k m " \pm c n , o c
bildirilen ve risendronat sodyum ile ili kili q n o o \tilde{A} , o m \tilde{A} p d a m u h t e m e l q n f w w
f \tilde{A} \tilde{A} p a d e m s g l a y l a r a c d a n k u v g n (p l a s e b o y a m v c k i n s i d a n s l a r p a r a n t e z k \pm k p f g
x g t k n o \pm k q m v " k t e k i l , 3 p 2 \pm \times p 3 1 \leq 1 / 1 0 0) ; = { c { i , p " ϱ \times δ d β c p 2 2 =
<1/100); seyrek * \times 3 1 3 2 . 2 2 2 \pm q m 1 \leq 1 / 1 0 0 0 0) ; b i l i n m i y o r (e l d e k i
verilerden hareketle tahmin edilemiyor)

Sinir sistemi j c u v c n , m n c t ,

[c { id, cp < c t , u ,

I ¾ j c u v c n , m n c t ,

[c { olmayan: iritis*

Gastrointestinal j c u v c n , m n c t ,

[c { ikonstipasyon, dispepsi, d w n cmpevtç, .ptdiyare .

[c { olmayan: gastrit, ¾ | q hdisfajikduodenit, ¾ | q h Ñ ñ g g r t

U g { t g m < " i n q u u k v . " ¾ | q h c i g c n " { c r , , m n , m

Kas- k u m g n g v " d q | w m n w m n c t . " d c " f q m w " x g " m g o k m "

[c { ikas pk < u m g n g v " c t , u ,

¥ q m " u g R t g m m w n c m " { q n w p f c " q u v g q e p k s i y o n t q | " * d k h q u h c

C t c v , t o c n c t

Seyrek: anormal m c t c fonksiyon testleri*

*Faz III osteoporoz ± c n , o c n insidan p cf " g c k n f, k m t n = , ' m " k ± k p " ¾ p e g ± c m a l a r d a k i a d v e r s o l a y / l a b o r a t u v a r / y e n i d e n m a r u z d , t c d n w o n c i o s a n c n , p r . o , v ,

Osteoporozlu postmenopozal m c f , p ñ Ñ p 5 f m g r i s e d r o n a t s o d y u m (n = 480) v e haftada 35 mg risedronat sodyumu (n = 485 mg) k a r , r a r b i r v { , n n , m . " ± k h v " m e r k e z l i b i r ± c n , g e n e k i f Ñ x ' g p e n t d e n e k e d i l e b i l i r l i k p r o f i l l e r i b e n z e r d i r . C c , f c m k i l a v e a d v e r s q n c { n c t " c t c v , k t n o c k e n k c n m k ' h k ç t q n l o ç p i f e n e p Ñ o m Ñ p a d v e r s o l a y l a r o l a r a k k a b u l e f k n o k " t c r q t " g f k n o k v k t " * k p u k f i t w d w p f c . " " 7 " o i " t k u g f t q p c v " u q r d i n t e s t i n a l " b a z u k l w k d w p c " i x g " c t , 0

Osteoporozlu erkeklerle t f g " k m k " { , n n , m " d k t " ± c n , o c f c . " v Ñ o " i v e p l a s e b o g r u b u n d a b e n z e r d i r . A d v e r s f g p g { k o n g t " f c j c i ¾ p n g p g p ñ g t f i b a r e t t i r .

N c d q t c v w x c : t D' c d h a s t a l a r d w n e c u m k a l s i y u m v e f o s f a t f Å | e { n e g e n , k p f g i e ± k e k . " c v e l a f i f a z a l m a o i e ¼ v t k Å m r . o Å v Å

Pazarlama u q p m e v u n , n c p , c d a f i , c a d v e r s g v m k n s e y r e k o l a r a k d k n f l i r t k n o k } u , b i l i n m e m e k t e d i r) :

D c , , m n , m " u k u v g o k " j c u v c n , m n c t ,

Bilinmiyor: Anafilaktik reaksiyon

I ¾ j c u v c n , m n c t ,

Bilinmiyor: iritis, Å x g k v

Hepato-bilier j c u v c n , m n c t ,

Bilinmiyor: E k f f k " m c t c e k g t " d q | w m n w m n c t , < " " T c r q t " | c o c p f c " m c t c e k g t " d q | w m n v Å t v Å p n ' g p g' k g g " q g f f e x v k " d

F g t k " x g " f g t k " c n v , " f q m w " j c u v c n , m n c t ,

Bilinmiyor: C p l k { q ¾ c f { g i o , . p " f ¾ m Å p v Å d c r i Å t g k m g k { ç x g n' c d t Å , n " n ¾ c f w { c t n f , g n t , k m " " t x g g c m u k { - J o h n s o n c s e n d r o f u x , g o k ' s i k e p i d e m a g l p e k r o l i z v e n ¾ m q u k v q m n c u v k m " x c u m Å n k v " k | q n g " t c r q t n c t , " f c j U c ± " f ¾ m Å n o g u k 0

Kas-iskelet bozukluklar, d c " f ç m v m g o k m " : j c u v c n , m n c t ,

Seyrek: C v k r k m " u w d v t q m c p v g t k m " x g " f k { c h k | g t " h g reaksiyon)

¥ q m " u g R t g m p o l i n d a c s t e ö n e k r o z * d k h q u h c p c v " u , p , h , " c f x g t u Bilinmiyor: Yene osteonekrozu

Å r j g n k " c f x g t u " t g c m u k { q p n c t , p " t c r q t n c p o c u , " T w j u c v n c p f , t o c " u q p t e g ç m u k Å { r q j p g m e c t " , l p n p ± " t c f x g t u v c , o c m v c f , t 0 " T c r q t n c o c " { c r , n o c u , . " k n c e , p " { q n c p c m " u c n c t 0 " U c n , m " o g u n g k " o g p u w r n c t , p , p H c t o c m q x k l k n c p u + ç O p g g t " m ç k k f k * t V o ç H n C g O t w k i t c k . g o v . t r ; g - m o g m v g posta: tufam@titck.gov.tr; tel: 0 800 314 00 08; faks: 0 312 218 35 99)

4.9. Doz a , ve tedavisi

Risedronat u q f { w o " f q | " c , o , " v g f d w k w p p g ö k m k c f i k p 0 u r g
F q | " c , o , p f c " u g t w o " m c n u k { w o " f Ñ | g { n g t k p k p " f Ñ
c { p , " | c o c p f c " j k r q m c n u g o k " d g n k t v k " x g " u g o r v q o n

T k u g f t q p c v , t ' k d i g f r t q p c n " x u g l ' f { w o w p " g o k n k o k p k " c | c r
m c n u k { w o " x g { c " c n Ñ o k p { w æ t k ð g g g p f k t p 0 ' k c p g o m g t ö
c , o , " q n i w n c t , p f c " g o k n o g o k " t k u g f t q p c v " u q f
{ c r , n o c u , r ' f Ñ Ñ p Ñ n g d k n k

5. HCTOCMQNQ'L\ MN'N MNGT

5.1. Farmakodinamik ¾ | g n n k m n g t "

H c t o c m q v g t c r ¾ v k m " i t w r < " D k h q u h q p c v n c t "
ATC kodu: M05 BA07

Etki o g m c p k | o c u , <

Risedronat sodyum kemikte j k f t q m u k e r c v k v g " d c n c p c p " d k t "
q u v g q m n c u v , p " p t g g f | g q p t " d q u n k f { w q p w w " p m w g " o d k c m u " m , n c o c m v c f , t
q u v g q d n c u v " c m v k x k v g u k " x g " m g o k m " o k p g t c n k | c u { q

Farmakodinamik etkiler:

M n k p k m " ¾ p e g u k " ± c n , o c n c t f c " t k u g f t q p c v " u q f {
c m v k x k v g u k " x g " f q | c " d c d k , { ' q q g m t p k n h ' m g o k g n ñ g n Ñ " v ñ
i ¾ u v g t k n o k v k t 0 " T k u g f t q p c v " u q f { w o w p " c m v k x k v g
f ¾ p i Ñ u Ñ p Ñ p " d k { q m k o { c u c n i l g " i ¾ q v g w ñ g p g o p d z a p k p 0 ' ¾ R
m c f , p n c t f c " { c r , n c p " ± d ¾ p i Ñ u Ñ p Ñ p " . d " k ¾ ' q m k d f c ' u m c g n
c | c n f - , 8 " , c " { x f g c " " 5 g p " Ñ u v " f Ñ | g { g " w Ñ p f g " , C E V Q P G N " g p ' ö ö
C E V Q P G N " 5 7 " o i " k n g " m g o k m " f ¾ p i Ñ u Ñ p Ñ p e i z e d k { q m k o
q n o w v w t 0

Osteoporozlu erkeklerle d k t " ± c m g o k m f d ¾ p i Ñ u Ñ p Ñ p " d k { q m k o { c u
azal o c n c t " 5 " c { f c p i ' ¾ | c n j g p ' o n k , u v c k ' u Ñ x g g ' f 4 6 " c { " i ¾ | n g p f l

Klinik etkililik ve i Ã x g p n k n k m <

Postmenopozal Osteoporoz Tedavisi:

FÃ Ã m " m g o k m " keÃ k m g w k p g t d Ã " Ã m " w p n w w . " " ¾ p e g m k
o g p q r q | . " u k i c t c " k ± o g " ¾ { m Ã u Ã q f q n q h ¾ { n Ã n u Ã k d k
Ã | g t g " r q u v o g p q r q | c n " q u v g q r q t q | n c " d c n c p v , n ,
O u v g q r q t q | w p " m n k p k m " u q p w e w t k n p k p h m c t f u t 0 n M , a t r
Lomber spinal KMY'daki ortalama de k k o " Ã | g t k p f g m k " g v { m , k n f g c t " k p g '
C E V Q P G N " 5 7 " o i " * p ? 6 : 7 + " " f q | w p " i Ã p n Ã m " C E V Q P G N "
r q u v o g p q r q | c n " q u v g q r q t q m ¾ w . " o n g e q m g p n n k i l e e ' c n , c r o a
i ¾ u v g t k n o k v k t 0

I Ã p f g " d k t " f g h c " w { i w n c p ikpp'bgtaik nisgdforatqsoyumu u q f { w o "
k c n ± c " x g " x g t v k g u d n t k c " n Ã | m g , t t k , p m f n g c m t k , " " g v m k u k p k " c t c v ,
q n c p " x g " q n o c { c p " g t m g p " x g r n e i n g g ' f k q w v d Ã p q Ã q | " 4 10 " 7
o i " f q | n c t , " c t c v , t , f n c o j , k n " " q d n Ã w a l Ã i y u l h m i c D w i t a m i n i t " " i m t w r n
* g g t " d c n c p i e ± " " c f n Ã o | , g e f i n v g t t f k g ' t d Ã ' c Ã h n x g " m u t a k n ± c " m , t ,
x g " t g n c v k h " t k u m k . " k n m " q n c { c " m e f c t " i g ± g p " | c o c

É K i r n c u g d q " m q p v t p q ? n 5 n 8 Ã 8 " 3 ± c " n , d r t e b r a l n i c p ' t i , , n i n v c c t " , x " q n c p " :
c n v , p f c m k " r q u v o g p q r q | c n " " c { n , t ' n o ' c u f Ã , t p g n { c n t g " " i Ã p f g " 7 " o i
risedronat sodyum yeni vertebral m , m n c t , " t k u m k p ¾ t ' g n ' q p v t n n o ' i t w d w 0
veya en az l vertebra m , t , , " d w n w p c p " m e f , p n c t f c " t ¾ n c v k h " t
q n o w v w t " " * { g p p k , " p x " g k t p v u g k d f t c c p n u " , m ' k , n t g , u l a n f e t t l e , p i v e v " u q f { w
' 3 3 0 5 " x g " r n c u g d q " k ' n " g 3 " 8 u 0 , 5 t " c q n , o { w n c v ' w ' t " + 4 } ; " 0 V 2 g " f x g k p
sonun f c " i ¾ t Ã o g { g D ' c d c n c n p c i o , ± v v c , " t ± 0 q m " u c { , y a r a r l a r m , t , , "
i ¾ u v g t k n o k v k t 0 " " I Ã p f g " 7 " o i " t k u g f t q p c v " u q f { v
d q { " m , u c n o c u , p , " f c " c | c n v o , v , t 0

É " m k " k m c q x p g v " t r q n n c n u Ã g " d ± q c n , o c { c " 9 2 " { c " Ã u v Ã p f g m k
x g " q n o c { c p " m e f , p n c - 1 9 " ; f " c c j t k c n u " , g p f f k c n " o q k n c v p k o r 0 h " g [o c w t , " d 9
< - 5 " U U " q n k q k ' p * k Ã p t " c t c n , , . c " p " , { n - 2 - 5 S k } m P e l 4 2 B i G l l v e ' K K K " m w n
r k u m " h c m v ¾ t Ã " d w n w p c p " m e f , p n c t " ± c n , o c { c " f c j k
f , , " t k u m " h c m v ¾ t Ã " d w n w p c p " x g { c " h g o w t " d q { p w p f
{ c , p f c m k " m a y a f n p p c d k n o k , n g t f k t 0 " " T k ü g n f t q p i a c g'
g v m k p n k k . " " k m k " v e f c x g k t " k i " t k w n d g w " " j * c 4 x 0 w 7 | c " p q i n c w a g v , w ' 7 ' w o

h c t m c " w n c o f c m k { 0 h p w ± n c t " q u v t g p r q n q t w p ç " i Ñ g è g n w { i w n c o c n c t n c " v c a p p o s t e r i o r e a n a l i z i n e " d a y a n p v o " c i n t w c r f n , c t t < , p "

- Femur boynu KMY T-u m q t-25 "SS (NHANES III) olan ve d c n c e m a z , b i r v c " x g t v g d t c n " m , t , , " d w n w p c p " j c u n v o c k n c r i s e d r o n a t p c " n v " i t w s o d y u m k o n t r o l g t w d w p c " i ¾ t g " m e k u m k p m k , " t ; m n c 8 t " , q | , q n " v o , r i s e d r o n a t s o d y u m 4 0 7 " x g " 7 " o i " i t w r n c t , p f c " m c n % c " m , t , m . 7.4);

-X g t k n g { c " j n e , q m ç n c t f c ' b u n d a n " d a h a 2 ü , p , t n , k o r q n m a c p " d k t " i ¾ | n g o n g p g d k n g e g k p k " f Ñ Ñ p f Ñ k d g n k m y k p " m c u n d a n " g n v f , , " h c m v ¾ t n g t k p " ¾ p g o k p k p " c t v o c u , p c " d c n , " q n D w " ± c n , o c n c t f c " u g m q p f g t " u q p n c v p t e b a l " n p , q t m , v c , u " , " q o l o c { c p . " f Ñ Ñ m " h g o d w t n " w p q p p w j " c M O f d w t f c n " v e x g " x g t v q n o c { c p " f Ñ Ñ m " h g o w t " d q { w p " g M O v [g) d w t " c d w " m w , p t c , p m " n j c t u , v c | c n f , , p , " i ¾ u v g t o k v k t 0

É " © ± " { , n " d q { w p e r i s e d r o n a t s o d y u m k o n t r o l g r u b u n d a n c o m u r g a , f e m u r b o y n u , t r o k a n t e r v e b i l c k t e m g o k m " o k p g t c n " { q w p n w w " * M t c f k w u " q t v c u , p f c " m g o k m " { q w p n w w p w " m q t w o w v w É I " Ñ p 5 f m g g d o z d a 5 " { , n n , m " t k u g f t q p c v " u q f { w o " v g f c x k u k f ¾ p i Ñ u Ñ " j , | , p f c " t k u g f t q p c v " u q f { w o w p " d c u m , n c {

É Ki- Ñ ± " d q { w p e c " i Ñ p f g " 7 " o i " f q | f c " t k u g f t q p c v " u m c f , p n c t f c p " b i y o p s i , ¾ p t p g " m m g g o t k k m " d k e m i k n g ¾ p k Ñ k Ñ p i f k g d " k ü t v f g t g e g f g i " ¾ u | v e g n t o k k g v f k t q p " c v " u q f { w o n w k e n g i k f n o r m a l u k " u , t c l a m g n n c t " { c r , f c " x g " o k p g t c n k | c u { q p w p f c " q n o w v x g t v g d t c n " d ¾ n i l e k f i k " m k u k p l u " k m f a t p c u m " p c p , { n c " d k t n k m v m c n k v g e u k n " w Ñ | u g v t | k " p g v m k n g t k " q n o c f , , p , " i ¾ u v g t o g m v

É " J g o " t s o d y u m f k u l l a n a n g r u p h e m d e k o n t r o l g r u b u n d a n o r t a d e r e c e d e v e c i d d i g a s v t q k p v g u v k p c n " { c m , p o c n c e n d o s k o p i i b u d g l ç d k t i t e g f ç j k ü v k n k m k n d u o d e n a l c x g t k h ¾ | c h c i w u i ¾ Ñ v n g g t k o k m c v p k o t g p " " d w p r i s e d r o n a t u q f { w o " i t w d w p f c " u g { t g m " q n c t c m " f w q f g p k v " i

Erkeklerde Osteoporoz Tedavisi:

Haftada bir kere 35 mg risedronat sodyumun, q u v g q r q t q | w " d w n w p c p " g t m g m c t c n , , " 5 8 " k (35 mg:risedronate sodyumüne 101) enp ,v p ,h f { , n n -d r k t " 4 k m ¾ t . " -m n q p w g d j q n Ñ " ± c n , o c f c " i ¾ u v g t k n o k v k t 0 " V Ñ c n o , n c t f , t 0

T k u g f t q p c v " u q f { w o " v g f c x k u k p k p " d c n e v , n o c u , p i ¾ t Ñ n o Ñ v Ñ t 0 " V g f r α k g f g p { " c 4 " " m { , { n c " u n c p " t j c c " h r v c f c " d k u q f { w o " c n c p " g t m g m n g t k p " d g n " q o w t i c u , . " h g o w t " c q n w o w v w t 0 " D w " ± c n , o c f c " c p v k h t c m v Ñ t " g v m k n k n T k u g f t q p c v " u q f { w o w p " m g ρ k m r g g " t D f V g O " " g f v Ñ m k o u g k u " k * D O g F t m c f , p n c t f c " d g p | g t f k t 0

R g f k { c v t k m " r q r Ñ n c u { q p < J c h k h " k n c " q t v c " f g t g e g f g " q u v g q l g p g | " k o r g t h g n r g f k { c v t k m " j c u v c n c t f c " t k u g f t q p c v -etiketli fedaw o w p " g v u q p t c u , " d k t " { , n " u m Ñ 4 t g . n " k - m n p k u t g " d t o m e n Ñ f l i q b a r k l e j m g r u p " ± k h v ± c n , Ñ o ± c " u f { g , + n " g " t n g p f k t k n o k - 5 v 2 k " m 0 i " " D c w " , ± c n n , , , o p c f c m " k 3 n 2 4 0 7 " o i " t k u g f t q p c v . " 5 2 " m i ' k Ñ g f t l q p p f g n l c m g t , " n Ñ p f f g

D w " d k t " { , n n , -m ¾ t c p -m n q p w g d j q n Ñ K h h v c | " ± c n , o c u , p , u q p t c . " r n c u g d q " i t w d w p c " m , { c u n c " t k u g f t q p c v " i t c p n c o n , " d k t " c t v , " i ¾ t Ñ a n r i s e d r o n a t Ñ r u b u n d a e n p a z l e m e n i r n c u g d m o r f o m e t r i k (X - , , p , " k n g " v c p , o n c p o , + " x g t v g d t c n " h t c r g t k { q f " u Ñ t g u k p e g " m n k p k m " h t c m v Ñ t " d k n f k t g p " r n c u g d q " i t w d w p f c " ' g t ; k 0 { 2 q " v k " f u k Ñ t " g C u = k , p m e " g g " v v k Ñ m o g " v j n d k u " v r c * c { " 3 4 " k n c " c { " 5 8 + " d c n c p i , ± v c " r n c u g d q " i t w d w p d c n c p i , ± v c " t k u g f t q p c v " i t w d w p c " t c p f q o k | g " q h t c m v Ñ t n g t " p l g m " f d r t d n o r k " v d p 0 ± f g t " j c h k h " k n c " q t v d w n w p c p " r g f k { c v t k m " j c u v c n c t f c " t k u g f t q p c v " u q f

5.2.Farmakokinetik ¾ | g n n k m n g t

Emilim:

Oral yoldan c n takiben absorpsiyon nispeten j , | n * , v f a , α z " " v e i h c e l e s e n d o z c v +

Oral dozda 2.5-30 mg; ± q doz ± c n , o c n c t ,
i 2.5 g 5 mg ve ayda ardarda iki i 75 mg kadar). Tablet in ortalama
oral d k { q { c t % t n c p v e o y i e c k l e r l e b i r l i k t e c n , p f , c | , c p n f o c c m v c f ,
D k { q { c t m d f n , c p e k l e r l e , h " c t m i n 3 / 4 , u n v , g n t o g o g m v g f k t 0

F c ; n , o

nsanlarda q t v c n c o c " m f c e t c , t m n , , o " " f j w c t e w o o k " " 8 0 5 q ' v n g l k m p i k) p f g , " t d c ' R
q t c y a k l a , ' m 4 6) v A t 0

Biyotransformasyon:

Risedronat sodyumun sistemik o g v c d q n d a i t j o k u m d e k t i r .

Eliminasyon:

Absorbe edilen dozun { c m n d c , t m u s a a t " k 4 ± 6 g t k i d a m a k a p f g y , n o b j r " x e
k p v t c d o z u n % 3 8 5 ' i 2 8 i A s o n r a i d r a r d a e l d e g f k n o r t a l a m a k r e n a l " k l e r e n s
105 ml/dak ve ortalama toplam klerens 122 ml/dak olup, aradaki fark
rnuhtemelen m g o k a d s o r p s i y o n a d c k l e r e n s l e i l g i l i d i r . R e n a l k l e r e n s
konsantrasyona d c a , k " n v e f k e r a l " k l e r e n s i l e k r e a t i n i n k l e r e n s i c t c u l i n e r f c "
bir ili ki x c t R e n a l k l e r e n s k o n s a n t r a s y o n a d c , f o g n , k n r e n a l k l e r e n s g i l e
kreatinin klerensi c t c u l i n e r f c d " k t " k x n c k t f o r k U y g u l a m a d a n s o n r a
konsantrasyon-zaman r t q h d i m i k a s y o n ± h c i 3 / 4 u v g o l u p t e r m i n a l g { c t , n c p o c
3 / 4 o 4 8 0 s a a t t i r .

Hastalara ait karakteristik 3 / 4 | g n n k m n g t <

Pediyatrik r q r A n c u { q p <

[c , " f g p " m o l a n A m a l a r d a t k u g f t f a r m a k o k i n e t i k 3 / 4 | g n n k m n g t k
c t c v , t . , n o c o , v ,

Geriyatrik p q r A n c u { q p <

F q | c c l { , c p t n c p o c u , p c " i g t g m " { q m v w t 0

Cinsiyet:

Oral w { i w n t a k i b e n o C E V Q P G N) k p " d k { q h { c c t t c c m q m k f g p ' k g l e "

erkeklerde c { p , f , t 0

G v p k m " M^{3/4} m g p " H c t m n , n , m n c t ,

L c r q p " r q r Ñ n c u { q p w p ÷ ÷ ' i 4 0 7 ÷ ÷ u ø p f m h k K u g f t q p ÷ m q p
w { i w n c p c p " d g { c | " , t m v c m k " u g t w o " m q p u c p v t c u { q p
f Ñ | g { f g " q n f w w " d g n k t n g p o k v k t 0 " H c t o c m q m k p g
t k u g f t q p c v ø , p " d g { c u h ç t h ÷ r 3/4 p Ñ x n Ñ x g f g j c " g v m k n k

D^{3/4} d t g m " { g v o g | n k k <

Risedronat d^{3/4} d t g m g v t { n c . " d Ñ g Ñ d e h ç t v c , p D f 3/4 c t d 0 t h g o m p m u k { q p n c
normal olan m k k m g t g kreatinin. klerensi yakla k, 30 mL/dk. olan hastalarda;
t k u g f t q p c v , p 'yaklag p, % 70' m n g p g p fi ku 'ç k r p v ç p Yeterli klinik t 0 "
deneyim o g x e w v " k n c k d i f d 3/4 d t g m o g (kreatinin klerensi yakla k, < 30
mL/dk.) mevcut olan j c u v c n c t f c " m w n n c p .edir.0Kreatinin" m n c g x t u g k p { u g k " g " f
30 mL/dk. olan hastalarda doz c { c t n ç arek yoktur. c

M c t c e k g t " { g v o g | n k k <

M c t c e k g t " o l a g v h a s t a l a r d a k t k u g f t q p c v ø m k n k Ñ k g p n k n k k
f g r l e n d i r m e k k ± k c p t c v { , c t r o , c n o c 0 , ± ø p t 0 v e m 3/4 s a n g m c t c e k g t
r t g r c t c a r a m v c , t t , , p n f t c k , u g , f p t f q c p " c v q p ö o g v c d q p U k , | ± g c v p , n t c 0 t f c
k p v t c y o l l a g v e r i l e h d o z u n ± q m " m Ñ k Ñ h n (± % u 0 1) u c h t c c " v k , ± n k o p , g " v , t 0 "
p g f g p n g . " m c t c e k o l a n h a s t a l a r d a " d d z q c | { w c m t n n w c k o y j c ' u k , v p ç w m o h t e m e l ,
i 3/4 t Ñ p o g o g m v g f k t 0

Asetil salisilik c u k v 1 n P U C n c p , e , n c t , <

F Ñ | g p n k a l l i s i l i k u a g i t v v e y m P U C m w n n c p , e , n c t , p f æ h ç * j n d h v ' c Ñ u v
gastrointestinal iste p o g { g p " q n c { n c t , p " k n p i l e t e d a v i c e d i l e n , h a s t a l a r d a g f t q p c
m q p v t q n " j e n z e d i r . c n c t , " k n e " d

7 0 5 0 " M n k p k m " 3/4 p e g u k " i Ñ x g p n k n k m " x g t k n g t k

U , ± v e p 3/4 r g m n g t f g " { c r , n c p " v q m u k m q n q l k m " ± c n , o c
f g k k m m g k " m d g t h , e c " g p | k o " c t v , n c t , " q d n c o i c m , " Ñ |
m c t c e k g t " i 3/4 t Ñ n n d Ñ D k w " Ñ u 0 " n g o n g k t k i s i p B i l i m m e n k e t e d i m n g "

p u c p n c t f c m k " v g t c r ^{3/4} v \tilde{A} m \tilde{A} n f g p | 'w q k' n h v c | t n n c u ^{3/4}, f' g p m n' c g u t t, c f m c' "
 v g u v k m \tilde{A} n g t " v q m u k u k v g " q t v c { c "k n , k m o n , k n k , " t \tilde{A} u "v M g u o q k n
 k t t k v c u { q p w " d b k f o s f o n a t l a r k d a b e k z e r o t k i l e r 0 ^{3/4} F \tilde{A} n g \tilde{A} " v \tilde{A} t 0 " " M n k p
 c \pm , m " q n o c o c m n c " d k t n k m v g " m g o k t i g p n g t f g d e' w | w p " u
 g v m k n g t " i ^{3/4} t \tilde{A} n o \tilde{A} v \tilde{A} n m \tilde{A} q \tilde{A} m m d k t p f k m n i' k n i' w \tilde{A} n t n g c o p g , " o v q m u k u k
 tedavi g f k n g p " u , \pm c p n c t , v e / v e { h e ^{3/4} " v w u h m m g o u m p f g c u " k g k m w k r h n g
 i ^{3/4} t \tilde{A} m i p o \tilde{A} a l s e m i " v e m o r t a l i t e i g d g u n c k p n k c " p f , t a d a r d a k i v v e r y t 0 | " V u & { , f c "
 v c x c p c " c k v " q n e c p n p e f e e 5 0 u n d a d a o 3 i 2 l ' m o i i l l i n \tilde{A} p 1 . i " \tilde{A} v p c " x f q
 v g t c v q l g p k v g " m c p , v , " t o k s i s i f e g d a h a g { f \tilde{A} k m u g g o n g " d e k e p t e s k e t t 0 , " p C p p g
 g p i g n " q n o w v w t m c' t l u g k p m q v l q m p u k k v p g i " v p d i x , g " d k e r k o p t " , ^{3/4} | g n "
 \pm , m c t o c o , v , t 0

6. HCTOCU " V \MNN MNGT

6.1. [c t f maddelerin listesi

Laktoz monohidrat

O k m t q m t k u v c n k | g " u g n \tilde{A} n q | "

Krospovidon

Magnezyum stearat

U c t , " f g o k t " q m u k v " G n 9 4

M , t o , | , " f g o k t " q m u k v " G n 9 4

Hipromelloz

Makrogol 400

J k f t q m u k r t q r k n u g n \tilde{A} n q |

Makrogol 8000

Silikon dioksit

Titanyum dioksit E171

6.2. Geimsizlikler

I g \pm g f t g n k k " n f k t 0

6.3. Raf ^{3/4} o t \tilde{A}

60 ay

6.4. Saklamaya { 3/4 p 3/4 n t ebbirler

25 Å E) qnkv, qafsc, m k m n u c m p d e , p , | 0

8 0 7 0 " C o d c n x g ", k p ±' g p k w e k n k k

M c t v q p " m w v w " k ± k p f g m k " g h h c h " R X E 1 c n Å o k p { w o " d n
4 film tabletlik blister ambalajlarda

6.6. V , d Å k Å p a r t g p a l a n m a d d e l e r i n k o j v e u f , k 3/4 g t 4 p n g o n g t

M w n n c p , n o Å c t o Å , p s n V , q h v t k m n c t , p " M q p v v e Å m Å a l a j [3/4 p g v o g n
Ambalaj C v , m n M e q t p , v p t 3/4 p Å v o g u y g a n o l a r Å k p i n g h a e d i l m e l i d i r .

7. RUHSAT U C J D

V g x c " n c ± n c t , " U c p 0 " x g " V k e 0 " C 0 0

Fatih Sultan Mehmet Mah. Poligon Cad.

Buyaka 2 Sitesi No: 8 C-Blok Kat: 3

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8. RUHSAT NUMARASI

2015/395

9. N R U H S A T V C T Å R U H S A T [G P N G V G T J

lk ruhsat tarihi: 18.05.2015

Ruhsat yenileme tarihi:

10. M © D) © K P N G P V G T J