will depend on the degree of physical dependence and the dose of the antagonist administered.

**PATIENT COUNSELING INFORMATION**

Physicians are advised to discuss the following issues with patients for whom they prescribe NUCYNTA® ER:

- Advise patients that NUCYNTA® ER should be taken only as directed and to report episodes of breakthrough pain and adverse experiences occurring during therapy to their physician.
- Advise patients not to adjust the dose of NUCYNTA® ER without consulting their physician *[see Dosage and Administration (2) in full Prescribing Information]*.
- Advise patients to inform their prescriber if they are experiencing changes in their pain level or if they feel they need a change in dosage.
- Advise patients that it may be appropriate to taper dosing when discontinuing treatment with NUCYNTA® ER as withdrawal symptoms may occur *[see Drug Abuse and Dependence]*.
- Advise patients that NUCYNTA® ER must be swallowed whole. The extended-release tablets may release all their contents at once if split, broken, chewed or crushed, or dissolved, resulting in a risk of fatal overdose of tapentadol.
- Advise patients that NUCYNTA® ER tablets should be taken one tablet at a time. Patients should not pre-soak, lick or otherwise wet the tablet prior to placing in the mouth. Advise patients to take each tablet with enough water to ensure complete swallowing immediately after placing in the mouth *[see Dosage and Administration (2) in full Prescribing Information]*.
- Advise patients using NUCYNTA® ER chronically (for several weeks) to contact their healthcare providers if they notice the need to increase dosing to treat symptoms of pain or they experience symptoms of withdrawal upon abrupt cessation of dosing.
- Advise patients to flush NUCYNTA® ER tablets that are no longer needed down the toilet. Advise patients to keep NUCYNTA® ER in the childproof container and store in a safe place to protect it from being stolen.
- Advise patients that NUCYNTA® ER is a Schedule II Controlled Substance and a potential drug of abuse. Patients should protect NUCYNTA® ER from theft, and NUCYNTA® ER should never be given to anyone other than the individual for whom NUCYNTA® ER was prescribed *[see Warnings and Precautions]*. NUCYNTA® ER tablets are intended for oral use only and must not be administered by any other route. If abused by parenteral routes, this may result in serious or even fatal complications *[see Abuse]*.
- Advise patients that NUCYNTA® ER can cause respiratory depression and hypotension *[see Warnings and Precautions]*.
- Advise patients to exercise caution about operating hazardous machinery, including automobiles while taking NUCYNTA® ER, as NUCYNTA® ER has the potential to impair judgment, thinking, or motor skills *[see Warnings and Precautions]*.
- Advise patients to notify their physician if they become pregnant or intend to become pregnant during treatment with NUCYNTA® ER *[see Use in Specific Populations]*.
- Advise patients not to breast-feed an infant during treatment with NUCYNTA® ER *[see Use in Specific Populations]*.
- Advise patients not to take NUCYNTA® ER while using any drugs that inhibit monoamine oxidase. Patients should not start MAOIs while taking NUCYNTA® ER.
- Advise patients that NUCYNTA® ER could cause seizures if they are at risk for seizures or have epilepsy. Such patients should be advised to use NUCYNTA® ER with care *[see Warnings and Precautions]*. Patients should be advised to stop taking NUCYNTA® ER if they have a seizure while taking NUCYNTA® ER and call their healthcare provider right away.
- Advise patients that NUCYNTA® ER could cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs (including Serotonin Reuptake Inhibitors, Serotonin and Norepinephrine Reuptake Inhibitors and tricyclic antidepressants) *[see Warnings and Precautions]*.
- Advise patients not to take alcoholic beverages, or prescription or non-prescription medications containing alcohol, while on NUCYNTA® ER therapy. The co-administration of alcohol with NUCYNTA® ER may result in increased serum levels and a potentially fatal overdose of tapentadol *[see Drug Interactions]*.
- Advise patients to inform their physicians if they are taking, or plan to take additional medications including CNS Depressants, MAO inhibitors, mixed agonists/antagonist opioid analgesics, anticholinergics, SSRIs, SNRIs, or tricyclic antidepressants *[see Drug Interactions]*.

See Medication Guide.

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# Kabuki syndrome, síndrome de Nikawa Kuroki o KMS

Se trata de un moderado a muy severo trastorno en el desarrollo fetal, descrito por dos grupos distintos de investigadores clínicos japoneses en el año 1981. Se han invocado posibles etiologías genéticas, epigenéticas, agresiones bioquímicas placentarias y/o todas juntas. Los primeros casos en los Estados Unidos y Europa se reportaron a partir de la década de los 90.

Los pacientes pueden presentar, aunque no en todos los casos, la tríada o secuencia de Robin (glosoptosis, micrognatia y hendidura palatina), paladar hendido, microstomía (labios unidos), macrostomia, conductos parotídeos ectópicos, frénula labial, sinequias entre el paladar duro y la lengua o la orofaringe, macroglosia, anquiloglosia, glándula tiroides ectópica (lingual), lengua depapilada, quistes y pseudoquistes papilares, mucoceles, ránulas, nódulos de Bohn, teratomas y coristomas de la cavidad oral, mioblastomas, quistes de Thornwaldt y otras deformaciones aún menos comunes de la cara y el cuello.

Suele acompañarse, aunque no en todos los casos, de otras malformaciones congénitas del sistema cardiovascular, el tracto urinario, el esqueleto, la piel y el sistema psicomotor. Aunque parezca paradójico, la mortalidad no es muy alta y la relación cognitiva y social de estos pacientes se conserva bastante bien, salvo en casos extremos.

El tratamiento es solo quirúrgico: reconstructivo, paliativo y sintomático. Se estima que hay, aproximadamente, un caso por cada 35 000 a 40 000 nacidos vivos. La evolución del síndrome en el adulto no ha sido bien estudiada.

El KMS, muy bien descrito científicamente en el niño, no tiene nada que ver con el denominado "síndrome de la máscara de Kabuki", "Kabuki effect" o rostro de Kabuki que suelen presentar las mujeres (y ahora también los caballeros) que abusan de las inyecciones de Botox con fines cosméticos.

En este caso, hablamos de la pérdida de expresión en la cara producida por la parálisis muscular facial y que recuerda a las máscaras del teatro tradicional japonés Kabuki. G