Product Profile for Educational Purposes

Analgesic nasal spray Target Product Profile

cessatech
rethinking child treatments

Sedare™ is a compounded drug product prepared by an FDA-registered 503B Outsourcing Facility operating under cGMP. It has not been evaluated or approved by the FDA for safety or efficacy. Use is based on a licensed practitioner's independent judgment and in compliance with applicable federal and state regulations.

VENTIS PHARMA

Based on ten years of clinical experience from leading hospitals in Scandinavia, Europe

Sedare is a nasal spray for acute pain treatment....

Ready to use - fixed combination of **Ketamine & Sufentanil**

TARGET PRODUCT PROFILE

1	**Indication** For relief of acute pain (moderate and severe) in children, age 1-17
2	**Efficacy** Rapid onset and minimal distress - needle-free administration
3	**Onset of action** Rapid onset of action (10-15 min)
4	**Safety** Acceptable safety - no need for special staff
5	**Posology** Two presentations - pending weight
6	**Handling** Simple to use and store at room-temperature – single use
7	**Instruction for use (IFU)** Prepare, dose – wait 15 minutes for potential 2nd dose

Unmet need

Acute & procedural pain in children
Several studies point to serious adverse long-term effects such as...

70%

of hospital medicine for children is off label use

Fear of future medical procedures and difficulty carrying out procedures

Frank et al.: *Parent and staff behavior, previous child medical experience, and maternal anxiety as they relate to child procedural distress and coping*. J Pediatr Psychol 1995;20:277-289

Reduced effectiveness of analgesics

Weissman et al.: *Consequences of inadequate analgesia during painful procedures in children*. Arch Pediatr Adolesc Med 1998; 152: 147-149)

Sensitization to future pain due to changes in how the nervous system processes pain

Taddio et al. :*The effects of early pain experience in neonates on pain responses in infancy and childhood*. Pediatr Drugs 2005;7:245-257)

Avoidance of medical care during adulthood

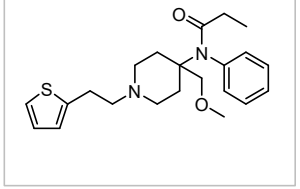
Pate et al.: *Childhood medical experience and temperament as predictors of adult functioning in medical situations*. Children's Health Care 1996;25:281-298

Large unmet need – only <30% receive treatments

MoA

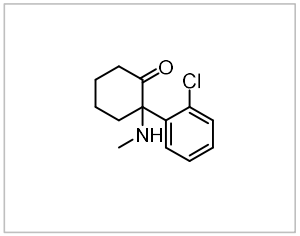
Creates a novel synergistic effect
Opioid dose may be lowered without reducing the analgesic effect

Sufentanil



An opioid used as an intravenous or sublingual analgesic under general anesthesia or in the recovery room

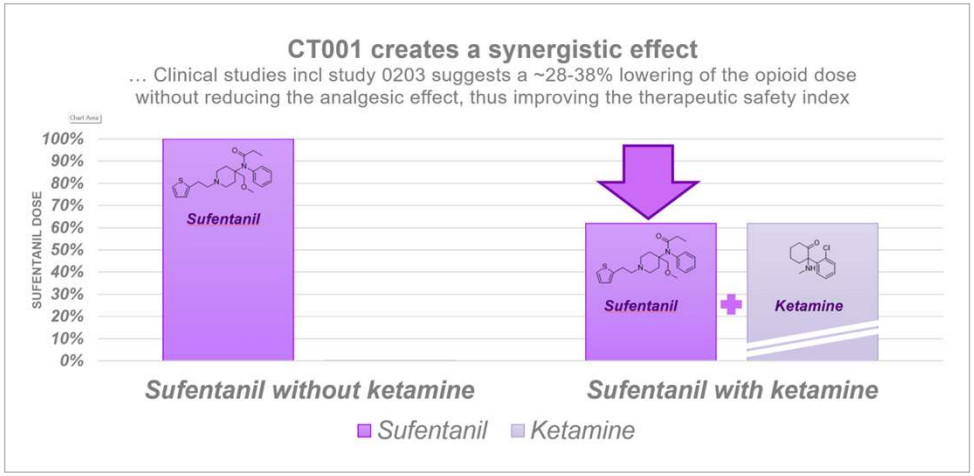
Ketamine



An N-methyl D-aspartate antagonist and a dissociative anaesthetic agent with analgesic effect at sub-anaesthetic plasma concentrations

1	Ketamine potentiates analgesic effect of opioids
2	Decreased doses and less side effects
3	Allows direct absorption to systemic blood supply, avoid hepatic first past metabolism

MoA synergistic effect



Dosing

Posology – age and weight adjusted
Two presentations with clear instructions

60 mcg / 60 mg Spray (50 µL) for Children 10 Kg to <30 Kg

Weight	*Approx age*	*Total No. sprays**	*Total Dose Delivered*
10 Kg - <15 Kg	1-3 years	2	6 mcg / 6 mg
15 Kg - <20 Kg	3-5 years	3	9 mcg / 9 mg
20 Kg - <30 Kg	5-9 years	4	12 mcg / 12 mg

90 mcg / 90 mg Spray (100 µL) for Children 30 Kg to ≥45 Kg

Weight	*Approx age*	*Total No. sprays**	*Total Dose Delivered*
30 Kg - <45 Kg	9-13 years	2	18 mcg / 18 mg
≥45 Kg	≥13 years	3	27 mcg / 27 mg

* Should be administered into alternating nostrils

One additional dose may be administered if adequate analgesia has not been achieved 15 minutes after the first dose

- Single use only – but each nasal spray contains up to two doses (at maximum sprays)
- The formulation is produced sterile and contains no preservatives (to follow paediatric guidelines)
- The vial and pump has specifically been selected and tested to fit with the fixed combination.

Benchmark

Competitive landscape is highly fragmented. No standard of care for acute and procedural pain in children

Competitive landscape	Midazolam	Nitrous Oxide	Opiods (sufentanil)	Fentanyl nasal spray	Ketamine/ s-ketamine	Sedare Sufentanil/ Ketamine
Route of Administration	Injection, oral or rectal	Inhalation	Injection, oral or rectal	Intranasal	Injection	Intranasal
Time to analgesic effect	N/A	~3 min	15 min (inj.) 1 h (other)	15 min	< 2 min	10 min (max 15 min)
Risk of side Effects	Moderate	Low	Low, dose dependent	Moderate	Moderate	Low, dose dependent
Authorized for Children	Only sedation > 1 year	Yes	Yes (no age range specified)	No	Yes (no age range specified)	Age 1-17
Food Restriction	Yes	Yes (2 hours)	No	No	Yes	No
Requires trained Staff	No	Yes	No	No	Yes	No
Comments	No analgesic effect	Working environment concerns	Fast onset Requires IV-access	No paediatric formulation	Requires anaesthetist	-